U.S. Department of Health and Human Services
National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID)

RFP-NIH-NIAID-DMID-08-05
"Division of Microbiology and Infectious Diseases: Regulatory Affairs Support"

OMB Control Number 0990-0115

1. **OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.** http://www.fedbizopps.gov/

2. **SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1**
NOTE: The issuance of this solicitation does not commit the government to an award.

3. **Issue Date:**	4. **Due Date:** October 29, 2007	5. **Small Bus. Set-Aside:** [ ]Yes [X] No **8(a) Set-Aside:** [ ]Yes [X] No **NAICS: 541990**
June 29, 2007	**Time:** 4:00 P.M., Eastern Standard Time	(See Part IV, Section L.)

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[ ] No [X] Yes (See Part IV, Section L.)	[X] Only 1 Award [ ] Multiple Awards	[ ] No [X] Yes (See Section J, Attachment 1, Packaging and Delivery of Proposal)

9. **Issued By:**	10. [x] **NIAID reserves the right to make awards without discussion.**	
Gehmelle L. Johnson Contract Specialist Office of Acquisitions, DEA, NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[X] No** **[ ] Yes** (See Part IV, Section L.)	12. **Period of Performance:** June 30, 2008-June 29, 2015

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Gehmelle L. Johnson **Phone:** 301- 451-3689 **Fax:** 301-480-4675 **E-Mail: gjohnson@niaid.nih.gov**	**Name: Yvette R. Brown** **Phone:** 301-496-0612 **Fax:** 301-480-4675 **E-Mail: ybrown@ niaid.nih.gov**	Charles Grewe Director, OA Address (see Block 9.)

16. **COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.**

17. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Part III, SECTION J – Attachments)

18. **DELIVERY ADDRESS INFORMATION**

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
Gehmelle L. Johnson Office of Acquisitions DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Gehmelle L. Johnson Office of Acquisitions DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with FAR 15.208 entitled "Submission, Modification, Revision, and Withdrawal of Proposals." FACSIMILE AND E-MAIL SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

PART I - THE SCHEDULE

PART I – THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR *(i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval)* WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Contractor shall provide regulatory expertise and technical and administrative support for the Division of Microbiology and Infectious Diseases (DMID) clinical research programs. The scope of activities to be performed includes review, preparation and submission of regulatory documents, reports and other agreements; design and conduct of regulatory educational and training activities; and the provision of specialized expertise and regulatory audits.

ARTICLE B.2. ESTIMATED COST

a. The estimated cost of this contract is $_____.

b. Total funds currently available for payment and allotted to this contract are $_____.

c. It is estimated that the amount currently allotted will cover performance of the contract through_____.

d. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; 9) Research Funding; and 10) Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the project officer, with a copy to the contracting officer, at least six (6) weeks in advance of the event. The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provided; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshment and/or meal costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held somewhere other than a government facility, provide an explanation of why the event is not being held at a government facility. Refer to NIH Manual Chapter 1160-1, Entertainment, for more information on NIH's policy on the use of appropriated funds for light refreshments and meals.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated March 13, 2007, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. (Please refer to Attachment 4, Reporting Requirements & Deliverables).

   For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s), 3 hard copies of these reports will be required as follows:

   (1) Monthly
   (2) Semi-Annually
   (3) Annually
   (4) Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

b. Other Reports/Deliverables

1. Source Code and Object Code

   Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR 52.227-11 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303 (a) (2)(ii) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303 (a) (2) (ii) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases

Office of Acquisitions
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer ad the address above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (**http://www.iedison.gov**), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION the Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at 6610 Rockledge Drive, Bethesda, MD 20892

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-5, Inspection of Services-Cost-Reimbursement** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the STATEMENT OF WORK Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule: ***Please refer to Reporting Requirements and Deliverables Attachment.***

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract. will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract:

b. The above items shall be addressed and delivered to:

Project Officer
Office of Regulatory Affairs (ORA)
Division of Microbiology and Infectious Diseases (DMID)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)

6610 Rockledge Drive, Room 6035
Bethesda, MD 20892-7630

Contracting Officer
Office of Acquisitions (OA)
Division of Extramural Activities (DEA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

Office of Policy for Extramural Research Office of Policy for Extramural (OPERA)
Office of Extramural Inventions and Technology Resources Branch (OETRB)
National Institute of Health (NIH)
6705 Rockledge Drive, Room 1040-A, MSC 7980
Bethesda, Maryland 20892-7980

NIAID Information System Security Officer (ISSO)
Office of the CIO
National Institute of Allergy and Infectious Diseases
National Institutes of Health
10401 Fernwood Road, Room 2SE04
Bethesda, MD 20892

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor) the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

(End of Clause)

The following individual (s) is/are considered to be essential to the work being performed hereunder:

NAME	TITLE
[To be specified prior to award]	

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified

below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

(1) Payment requests shall be submitted as follows:

One original to the following designated billing office:

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

2) In addition to the requirements specified in FAR Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all payment requests:

(a) Name of the Office of Acquisitions. The Office of Acquisitions for this contract is **NIAID**.

(b) Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is **NIAIDOAInvoices**.

(c) Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of Standard Form 26. **(Note: This only applies to new contracts awarded on/after June 4, 2007, and any existing contract modified to include the number.)**

(d) DUNS number or DUNS+4 that identify the Contractor's name and address exactly as stated on the face page of the contract.

(e) Identification of whether payment is to be made using a two-way or three-way match. This contract requires a **two-way** match.

b. Inquiries regarding payment shall be directed to the designated billing office, (301) 496-6088.

ARTICLE G.4 LETTER OF CREDIT PAYMENT INFORMATION

a. Advance payments will be provided under Letter of Credit Number_____
In accordance with FAR 32.406 Letters of Credit, Part 6, Chapter 2000 of the Treasury Financial Manual, and Department of Treasury Circular 1075 (31 CFR Part 205, http://www.access.gpo.gov/nara/cfr/waisidx_00/31cfr205_00.html.

The contractor shall withdraw cash only when needed for disbursements and report cash disbursements and balances in accordance with the CONTRACT FINANCIAL REPORT ARTICLE in Section G of this contract. The contractor shall impose the same standards of timing and amount upon any subcontractors, including the furnishing of reports of cash disbursements and balances. Failure to adhere to these provisions may cause the Government to withhold further withdrawals under Letter of Credit.

1. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contract, NIH (RC)-1, are attached and made a part of this contract for the submission of completion

and/or final invoices. The invoice instructions and the following directions fort he submission of invoices/financing requests must be followed to meet the requirements of a "proper" invoice, pursuant to FAR 32.9. The completion and/or final invoice shall be submitted as follows:

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

2. Inquiries regarding payments should be directed to the following office administering advance payments (301) 496-6088.

ARTICLE G.5. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.6. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication entitled, **Contractor's Guide for Control of Government Property**, which can be found at:

http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached

between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.2. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

ARTICLE H.3. ANTI-LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet,

booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

ARTICLE H.4. PRIVACY ACT, HHSAR 352.270-12 (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S. C. 552a (m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C 552a (i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as HHS employees. These provisions also apply to all subcontracts awarded under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)).

The contract work statement: (a) Identifies the system(s) of records and the design, development, or operation work to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http:www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html.

The Privacy Act System of Records applicable to this project is Number 09-25-0115. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: **http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm**.

ARTICLE H.5. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, dated _TBD_ is attached hereto and made a part of this contract.

(2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS)" at http://www.esrs.gov.

(1) Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the Contract Specialist shall be included as a contact for notification purposes at the following e-mail address:

gjohnson@naid.nih.gov
Gehmelle L. Johnson, Contract Specialist, OA, NIAID, NIH

ARTICLE H.6. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract

funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b. **Public Law and Section No.***	**Fiscal Year***	**Dollar Amount of Salary Limitation***

c. Payment of direct salaries is limited to the Executive Level rate which was in effect on the date(s) the expense was incurred.

[*Applicable information to be included at award]

ARTICLE H.7. INFORMATION SECURITY

The Statement of Work (SOW) requires the contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA_final.pdf

a. Information Type

[X] Administrative, Management and Support Information:

http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf

[ ] Mission Based Information:

http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf

b. Security Categories and Levels

Confidentiality	Level:	[ ] Low	[X] Moderate	[ ] High
Integrity	Level:	[ ] Low	[X] Moderate	[ ] High
Availability	Level:	[ ] Low	[X] Moderate	[ ] High
Overall	Level:	[ ] Low	[X] Moderate	[ ] High

c. Position Sensitivity Designations

(1) The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

[X] Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

(2) The contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at:

http://www.hhs.gov/ocio/policy/index.html#security

Upon receipt of the Government's notification of applicable Suitability Investigations required, the contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NAID Information Technology Security Policies, Background Investigation Process" website:

http://www.hhs.gov/ocio/policy/index.html#security

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(3) Contractor/subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/subcontractor employees may begin work under the contract after he contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c.(2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the contractor/subcontractor employee to work under the contract.

d. Information Security Training

The contractor shall ensure that each contractor/subcontractor employee has completed the NIH Computer Security Awareness Training course at: http://irtsectraining.nih.gov/ prior to performing any contract work, and thereafter completing the NIH specified fiscal year refresher course during the period of performance of the contract.

The contractor shall maintain a listing by name and title of each contractor/subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by contractor/subcontractor staff shall be included on this listing. See Article C.2. Reporting Requirements.

e. Rules of Behavior

The contractor/subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: http://irm.cit.nih.gov/security/nihitrob.html.

f. Personnel Security Responsibilities

Contractor Notification of New and Departing Employees Requiring Background Investigations

(1) The contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer within fiver working days before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.

(2) New employees: Provide the name, position title, e-mail, and address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the government will determine the appropriate security level.

(3) Departing employees:

Provide the name, position title, and security clearance level held by or pending for the individual.

Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a contactor/subcontractor employee terminates Work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

(1) Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 8 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
-18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

(2) Contractor-Employee Non-Disclosure Agreements

Each contractor/subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

h. NIST SP 800-26 Self-Assessment Questionnaire

The contractor shall annually update and re-submit its Self-Assessment Questionnaire required by NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and

System Reporting Form (http://csrc.nist.gov/publications/drafts/Draft_sp800_26Rev1.pdf - See Appendix B for format).

Subcontracts: The contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the SOW to (1) develop a Federal information system(s) at the contractor's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the contractor's/subcontractor's facility.

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer.

i. Information System Security Plan

The contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, *Guide to Developing Security Plans for Federal Information Systems*.

(http://csrc.nist.gov/publications/nistpubs/800_18_Rev1/sp800_18_Rev1_final.pdf). The details contained in the contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The contractor shall include similar information for any subcontractor performing under the SOW with the contractor whenever the submission of an ISSP is required.

ARTICLE H.8. STORAGE FACILITY REQUIREMENT AND CERTIFICATION

The contractor shall ensure that all materials generated under this contract for which commercial records storage is required, shall be stored in a facility that meets National Archives and Records Administration (NARA) requirements for safe, secure and certified storage as required by 36 CFR 1228, subpart K.

The contractor shall provide the contracting officer with the names(s) and location(s) of the commercial records storage facility used to store materials under this contract. In addition, the contractor shall provide a copy of the “Facility Standards for Records Storage Facilities Inspection Checklist”, self-certifying that the facility being used to store federal records meets established NARA standards. NARA standards are available at http://www.archives.gov/about/regulations/part-1228/k.html.

Sixty (60) days prior to contract end date, the contractor shall submit to Project Officer and Contracting Officer, an inventory of all materials stored. The disposition of these materials shall be determined no later than the expiration date of the contract.

ARTICLE H.9. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY HHSAR 352.270- 19(b) (January 2006)

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by Public Law 105-220 under Title IV (Rehabilitation Act Amendments of 1998), all Electronic and Information Technology (EIT) developed, procured, maintained, and /or used under this contract shall be in

compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/sec508/standards.htm.

The standards applicable to this requirement are identified in the Statement of Work.

Venders may document conformance using industry-standard Voluntary Product Accessibility Template at **http://www.itic.org/archives/articles/20040506/faq_voluntary_product accessibility_template_vpat.php**]. Vendors should provide detailed information necessary for determining compliance, including defined contractor-incidental expectations.

ARTICLE H.10. ENERGY STAR REQUIREMENTS

Executive Order 13123, "Greening the Government Through Efficient Energy Management" and FAR 23.203 require that when Federal Agencies acquire energy using products, they select, where life-cycle cost-effective, and available, ENERGY STAR or other energy efficient products.

Unless the Contracting Officer determines otherwise, all energy-using products acquired under this contract must be either an ENERGY STAR or other energy efficient product designated by the Department of Energy's Federal Energy Management Program (FEMP).

For more information about ENERGY STAR see **http://www.energystar.gov/**
For more information about FEMP see http://eere. energy.gov/

ARTICLE H.11. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR **Clause 352.224-70**, **Confidentiality of Information** (January 2006): See Section C.4. of the Statement of Work.

ARTICLE H.12. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause 352.270-6, Publications and Publicity incorporated by reference in SECTION I of this contract, the contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No TBD. .

[Applicable information to be included at award]

ARTICLE H.13. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS** (**1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General

Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.14. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clauses:

1. Service involving the use of Information Technology

YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

ARTICLE H.15. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principle and Guidelines for Recipients of NIH Research Grants and Contracts, "(Federal Register Notice, December 23, 1999 [64 FR 72090], concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: http://ptt/od.nih.gov/NewPages/64FR72090.pdf is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools," and "research resources" are used interchangeably and have the same meaning.

ARTICLE H.16. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at:
http://www.usfa.fema.gov/hotel/index.htm

ARTICLE H.17. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

The Policy requests that beginning May 2, 2005, NIH-funded investigators submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's

final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at:
http://grants.nih.gov/grants/guide/notice_files/NOT_OD_05_022.html.

ARTICLE H.18. CONSTITUTION DAY

Each educational institute that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING **ARTICLE I.1 GENERAL CLAUSE LISTING(S)** WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

General Clauses for a Cost-Reimbursement Research and Development Contract

The complete listing of these clauses may be accessed at:
http:/rcb.cancer.gov/rcb-internet/appl/general-clauses/clauses.jsp

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

Alternate IV (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.

FAR Clause **52.216-7, Allowable Cost and Payment** (December 2002), is modified in paragraph (a) to delete the words “subpart 31.2 of the Federal Acquisition Regulation(FAR)” and substitute the words “45 CFR part 74, appendix E”.

Alternate II (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (September 2006) is added.

FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefore. ***[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]***

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

(1) FAR Clause **52.217-2, Cancellation Under Multiyear Contracts** (July 1996).

(2) FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

(3) FAR Clause 52.227-14, **Rights in Data-General** (June 1987)

(4) **Alternate V** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

Specific data items that are not subject to paragraph (j) include: None

(5) FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).

(6) FAR Clause **52.230-6, Administration of Cost Accounting Standards** (April 2005).

(7) FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

(8) FAR Clause **52.245-19, Government Property Furnished "As Is"** (April 1984).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

(1) HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).

(2) HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

(1) **NIH (RC)-7, Procurement of Certain Equipment** (April 1984) (OMB Bulletin 81-16).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)

(a) Definition. As used in this clause--

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to

employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR Part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B-Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR Part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov ; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR Part 470, Subpart B-Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
ATTACHMENT 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
ATTACHMENT 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP
ATTACHMENT 3:	Statement of Work	See Attachment Section at the end of this RFP
ATTACHMENT 4:	Reporting Requirements	See Attachment Section at the end of this RFP
ATTACHMENT 5:	Additional Technical Proposal Instructions and Format for Technical Proposal	See Attachment Section at the end of this RFP
ATTACHMENT 6:	Additional Business Proposal Instructions and Uniform Cost Assumptions	See Attachment Section at the end of this RFP
ATTACHMENT 7:	Current DMID Clinical Research Programs	See Attachment Section at the end of this RFP
ATTACHMENT 8:	DMID Funded Clinical Research Support Services Contracts	See Attachment Section at the end of this RFP

TECHNICAL PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal.)

Title	Location
Technical Proposal Cost Summary	http://www.niaid.nih.gov/contracts/forms.htm
Summary of Related Activities	http://niaid.nih.gov/contract/forms.htm
Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms./form7.pdf
Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb_internet/forms/nih1688_1.pdf
Information Technology Systems Security-Prospective Offeror Non-Disclosure Agreement	http://rcb.cancer.gov/rcb-internet/forms/IT-security-nondisclosure.pdf

BUSINESS PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Business Proposal.)

Title	Location
Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/forms.htm
Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Certificate of Current Cost or Pricing Data	http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf
Wage Rate Determination: Washington D.C./Baltimore	http://rcb.cancer.gov/rcb-internet/forms/WR-DC-5-23-2005(94-2103).pdf http://rcb.cancer.gov/rcb-internet/forms/WR-Balt-5-23-2005(94-2247).pdf
Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance.)

Title	Location
Invoice/Financing Request Instructions--Cost-Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-intrenet/forms/rc4.pdf
Privacy Act System of Records System of Records No. 09-25-0115 is applicable to this RFP	http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm
Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Government Property Schedule	http://www.niaid.nih.gov/contact/forms/form9.pdf
Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls

Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:

1. Go to the Online Representations and Certifications Application (ORCA) at: https://orca.bpn.gov/ and complete the Representations and Certifications; and

2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address:
http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2004)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show—

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225_17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data

subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those sited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iv) A summary of the rationale for award.
(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **"JUST IN TIME**"

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy. The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision.

Annual Report. The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision.

Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their final proposal revision.

Subcontracting Plan. The offeror's Small Business Subcontracting Plan shall **not** be submitted with the initial business proposal. Only the apparent successful offeror will be required to submit **an acceptable** subcontracting plan.

Cost/Pricing Information. The offeror's business proposal shall include the basic cost/pricing information specified in Section L.2.c.(1) of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. [The information may also include submission and certification of cost or pricing data.]

c. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541990.

(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

d. **TYPE OF CONTRACT AND NUMBER OF AWARDS**

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement type completion contract with a term of 7 years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 9.2 full time equivalents. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. **SERVICE OF PROTEST** (SEPTEMBER 2006) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Charles Grewe
Director, Office of Acquisitions
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
6700 B Rockledge Dr. Room 3214
Bethesda, MD 20892

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

l. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it appears to offer the best value to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD.)

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY). However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, Section M of this RFP.

(7) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(8) **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(9) **Selection of Offerors**

a) The acceptability of the [scientific and] technical portion of each [research] contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the

opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

(10) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the

NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the

Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(11) **Past Performance Information**

a) Offerors shall submit the following information as part of their business proposal.

A list of the last three (3) contracts completed during the past three (3) years and all contracts currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract over $650,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b) The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(12) **Electronic and Information Technology Accessibility, HHSAR 352.270-19 (a) (January 2006)**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by Public Law 105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, procurement, maintenance, and/or use of EIT products/services; therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards. Information about Section 508 is available at http://www.section508.gov .

(End of Provision)

(13) **Solicitation Provisions Incorporated by Reference,** FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
b) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
d) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks

1) Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Project Objectives, NIH-1688-1**

The offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an **Institution of Higher Education:** The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, **"INSTRUCTIONS:"**

b) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

(c) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Single Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume

does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in SECTION M - Evaluation Factors for Award of this solicitation.

3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

5) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

6) (a) **Sharing Research Data**

*[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]*

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

c. BUSINESS PROPOSAL INSTRUCTIONS

1) **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2) **Proposal Cover Sheet**

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

a) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $650,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for

establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

   If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

    List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

11. **Cost and Pricing Data**

Note: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.

1. **General Instructions**

A. You must provide the following information on the first page of your pricing proposal:

(1) Solicitation, contract, and/or modification number;
(2) Name and address of offeror;
(3) Name and telephone number of point of contact;
(4) Name of contract administration office (if available);
(5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
(6) Proposed cost; profit or fee; and total;
(7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
(8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
(9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR15.403_5(b)(1) and Table 15_2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data,regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
(10) Date of submission; and
(11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including-

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
(2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services**. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver).

Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $11.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you (to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB_CMF and show the calculation of the proposed amount (see FAR 31.205_10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments).

For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

[NOTE: Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) should not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.]

6. **Salary Rate Limitation in Fiscal Year 2007**

Offerors are advised that pursuant to **P.L. 110-005**, no NIH Fiscal Year 2007 (October 1, 2006 - September 30, 2007) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L.

110-005 applies only to Fiscal Year 2007 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. **110-005** states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES:
http://www.opm.gov/oca/06tables/indexSES.asp

***Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2007 Executive Level I Salary rates.*

Pending Law 110-005, Revised Continuing Appropriations Resolution, 2007, extends the legislative provisions provided in the FY2006 Appropriations Act (Public Law 109-149) through the end of FY2007. Therefore, the provision that restricts the amount of direct salary to Executive Level I of the Federal Executive Pay Scale continues through FY2007. The Executive Level I annual salary rate was $183,500 for the period January 1 through December 31, 2006. Effective January 1, 2007, the Executive level I salary rate increased to $ 186,600.

Alternate I (October 1997) of FAR Clause **52.215-20**, **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** (October 1997). As prescribed in 15.408(l), **substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:**

> (b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:
>
> The format specified in paragraph [L.2.c.(4)] Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(7) **Small Business Subcontracting Plan**

This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.

If the proposed contract exceeds a total estimated cost of $550,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $550,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

___% for Small Business; ___% for Small Disadvantaged Business; ___% for Women-Owned Small Business; ___% for HUBZone Small Business; and ___% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(8) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(9) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $550,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). TheNAICS codes can be found at: http://www.sba.gov/size .

The Department of Commerce website for the annual determination for NAICS codes* is: http://www.arnet.gov/References/sdbadjustments.htm.

**Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines “Contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(10) **Total Compensation Plan**

a) **Instructions**

NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.

1) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors included in the competitive range will be required to submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

2) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

3) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b) **Evaluation**

1) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements.

The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(11) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process.

Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(12) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

(b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38**, (May 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232_34, Payment by Electronic Funds Transfer-Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9_digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9_digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on_line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

e) **Incremental Funding, HHSAR 352.232-75, Incremental Funding (January 2001)**

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds as specified in FAR 52.232-22. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modifications. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of periodic allotments, nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in the Section I, Contract Clauses.

(End of provision)

f) **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(13) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).
b) What priority the work will be given and how it will relate to other work.
c) The amount of time and facilities available to this project.
d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.
f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(14) **Proposer's Annual Financial Report**

NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(15) **Representations and Certifications - SECTION K**

One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at: http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

(16) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. **GENERAL**

The major evaluation factors for this solicitation include technical (which encompasses experience and past performance factors) cost/price factors and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are approximately equal to cost or price. In any case, the Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. **TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERIA	**WEIGHT**
Criterion 1: Technical Approach	**40**

The offeror's understanding of the technical requirements of the Statement of Work as evidenced by the soundness, appropriateness, adequacy, and feasibility of the following:

A. Review, Preparation, and Submission of Regulatory Documents, Reports and Other Agreements

1) *Regulatory Submissions*: (i) proposed plans and procedures for reviewing specific study products and clinical and non-clinical documents for regulatory compliance and adequacy in support of Investigational New Drug (IND) applications, Master Files (MFs) and Investigational Device Exemptions (IDEs);(ii) identification of key features to address and common errors and deficiencies uncovered in the review of such documents; (iii) examples of recommendations provided by the offeror for correcting common errors and deficiencies; and (iv) relevance of previous regulatory submissions prepared by the offeror with respect to the scope of clinical research to be supported under the contract and the ability to accommodate a large volume of submissions based on recent organizational experience.

2) *Investigator Brochures (IBs) and Environmental Assessment Exemption Statements*: (i) proposed plans and procedures for preparing and updating IBs and for preparing environmental assessment exemption statements; (ii) identification of key features to address in the preparation of such documents and common problems encountered in assessing and arraying the results of pre-clinical and clinical testing; and (iii) sample

table of contents for IBs and list of IBs and environmental assessment exemption statements prepared by the offeror.

3) *IND, MF and IDE Annual Reports*: (i) proposed procedures for the preparation of IND, MF and IDE Annual Reports; (ii) identification of common problems encountered in preparing narrative analyses and tabular summaries based on existing clinical trial data and approaches used to resolve common problems; and (iii) relevance of Annual Reports prepared by the offeror with respect to the scope of clinical research to be supported under the contract and the ability to accommodate a large volume of such reports based on recent organizational experience.

4) *FDA Meetings, Teleconferences and Correspondence*: (i) organizational experience with assisting in the preparation of pre-IND/IDE/MF briefing packets for the FDA and other regulatory authorities with respect to the scope of clinical research to be supported under this contract and the ability to accommodate a large volume of such pre-briefing packets: (ii) identification of key features of investigational products and clinical trials to be addressed in pre-briefing packets, problems encountered and approaches to resolve problems; and (iii) organizational experience with arranging for, participating in and preparing summaries of meetings and teleconferences, pre- and post-submission, including assisting in responding to inquires and requests for additional information from regulatory authorities.

5) *Regulatory Affairs Tracking and Reporting*: (i) proposed plans and procedures for: indexing all regulatory submissions and associated correspondence/materials; tracking key dates; maintaining and tracking contact information; reporting on regulatory activities; and filing and tracking various agreements between DMID and product manufacturers; and (ii) organizational experience with assisting in the preparation of responses to requests for information from various sources.

B. Regulatory Educational and Training Activities

1) Proposed plan for the conduct of a one-day training workshop for clinical site staff at domestic and international sites on compliance with Good Manufacturing Practice (GMP) and Good Laboratory Practices (GLP) with respect to regulatory requirements and guidelines governing research involving human subjects.

2) Organizational experience in designing, conducting and providing logistical support for regulatory training activities using multiple mechanisms, and in designing and conducting participant assessments and making improvements based on such assessments.

C. Specialized Expertise and Regulatory Audits

1) *Specialized Expertise*: Proposed plans for and organizational experience in providing specialized expertise in the following areas: non-U.S. regulatory requirements and guidelines; assay development and validation; GLP and GMP; pharmacology and product formulation; toxicology; and statistical analysis for non-clinical studies.

2) *Regulatory Audits*: Proposed plan for performing regulatory audits and organizational experience in providing and/or overseeing the provision of such services through consultants and/or subcontractors, including tracking and reporting on all audit activities.

D. Electronic Information Systems, Data Management, and System Security

1) Proposed plan for and organizational experience in maintaining and operating database information systems, including software and hardware used by the offeror and all proposed subcontractors for projects of the same or similar scope, complexity and requirements, and problems encountered in system maintenance, operation and security.

2) Proposed plan for and organizational experience in coordinating regulatory affairs support functions with other clinical research support contractors with respect to tracking and reporting on the status of INDs, MFs, IDEs and clinical protocols, documenting receipt of essential regulatory documents for shipping of clinical agents, and obtaining clinical data for preparation of IND, IDE and MF Annual Reports.

3) Organizational experience in electronic submission of regulatory documents, discussion of previous problems and anticipated problems for expansion of the use of electronic submissions, and proposed approaches for resolution.

4) Organizational experience with and proposed plan for meeting NIH Information Security requirements and HHS Secure One-Information Security Program Policy (http://intranet.hhs.gov/infosec/policies_guides.html).

E. Quality Assurance/Quality Control (QA/QC): Proposed QA/QC plan to standardize contract processes, including: template for and list of Standard Operating Procedures (SOPs); plans for annual staff training; procedures for maintenance of validation status of equipment and computer software; plans for documenting adherence to all applicable requirements; and record retention and storage procedures.

F. Initial and Final Transition: Adequacy and appropriateness of the proposed plans for the initial and final transition of contract materials, databases and equipment, including approaches to ensure that there is no loss of time or interruption to the conduct of ongoing DMID-funded clinical research and clinical research in development during the transition period.

Criterion 2: Scientific and Technical Personnel 35

A. Principal Investigator (PI): Appropriateness and adequacy of the education, training, experience, expertise and effort of the proposed PI, including experience with projects of similar size and complexity, with respect to the following:

1) Regulatory requirements and guidelines, both domestic and non-domestic, governing the conduct of research involving human subjects.
2) Preparation and review of clinical and non-clinical regulatory documents and requirements for specific study products for submission of INDs, MFs and IDEs to the FDA and other regulatory authorities, and preparation of narrative analyses and tabular summaries for IND, MF and IDE Annual Reports.

3) Preparation of pre-IND/MF/IDE briefing materials and participation in meetings and teleconferences with the FDA and other regulatory authorities and preparation of meeting/teleconference summaries.
4) Design and conduct of regulatory educational and training activities.
5) Management, oversight and system security for databases and information systems for tracking and reporting on regulatory activities, including coordination with other clinical research support contractors.
6) Provision of specialized expertise and regulatory audits directly or via consultants/subcontractors.
7) Working with product manufacturers on regulatory submissions and reporting and with clinical study site personnel on adherence to regulatory requirements and guidelines.
8) Coordination, management and QA/QC processes and standard operating procedures.

B. Other Scientific and Technical Personnel: Appropriateness and adequacy of the education, training, experience, expertise and effort of the proposed scientific and technical personnel of the offeror and all proposed consultants/subcontractors, including experience with projects of similar size and complexity and the adequacy of the proposed mix of staff, expertise, experience and training, with respect to the following:

1) review, preparation, submission and reporting for regulatory submissions and pre-briefing materials for the FDA and other regulatory authorities.
2) the collection, coding, storage and tracking of regulatory documents, correspondence and other materials, and the preparation of routine and ad hoc reports on the status of regulatory activities and action items.
3) the design, conduct and evaluation of regulatory training activities for Government and clinical study site staff.
4) specialized expertise, including expertise in chemistry, microbiology and product manufacturing, with respect to: non-U.S. regulatory requirements and guidelines; assay development and validation; GLP and GMP; pharmacology and product formulation; toxicology; and statistical analysis of non-clinical data.
5) information technology expertise to support: the maintenance and operation of databases, back-up systems and system security procedures; interface with other clinical research support contractors; evaluation of new and improved technologies and implementation of system upgrades/modifications; and programming and set-up of regulatory information systems and training for government staff.

Criterion 3: Facilities, Equipment and Other Resources 15

The availability and adequacy of the facilities, equipment and other resources of the offeror and all proposed subcontractors for the conduct of the regulatory affairs support functions specified in the Statement of Work, including hardware and software for the maintenance and operation of the DMID Regulatory Management Database System, back-up systems, system security, and interfacing with DMID clinical research support contractors to access, transmit and store data.

Criterion 4: Project Management 10

A. Adequacy of the plans for the staffing, organization, distribution of responsibilities, leadership, coordination and lines of authority for carrying out contract requirements.
B. Suitability of systems proposed for tracking contract activities and monitoring progress, timelines and budgets.

C. Suitability of plan for how the PI will communicate with the Project Officer and Contracting Officer, as well as established lines of communication with product manufacturers, clinical study sites, and other DMID clinical research support contractors.
D. Suitability of the plan for safeguarding the confidentiality and intellectual property of data and materials provided under the contract.

TOTAL POSSIBLE POINTS: 100

3. **PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

The following rating method shall be used in the evaluation of past performance information:

+2 **Excellent** - Based on the offeror's performance record, no doubt exists that the offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the offeror's performance was superior and that they would unhesitatingly do business with the offeror again.

+1 **Good** - Based on the offeror's performance record, little doubt exists that the offeror will successfully perform the required effort. Sources of information state that the offeror's performance was good, better than average, etc., and that they would do business with the offeror again.

0 **None** - No past performance history identifiable.

-1 **Marginal** - Based on the offeror's performance record, some doubt exists that the offeror will successfully perform the required effort. Sources of information make unfavorable reports about the offeror's performance and express concern about doing business with the offeror again.

-2 **Poor** - Based on the offeror's performance record, serious doubt exists that the offeror will successfully perform the required effort. Sources of information consistently stated that the offeror's performance was entirely unsatisfactory and that they would not do business with the offeror again.

4. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments applicable to this RFP as specified in SECTION J - List of Attachments

ATTACHMENT 1
PACKAGING AND DELIVERY OF THE PROPOSAL

Your proposal shall be organized as specified in Section L.2., "Instructions to Offerors" - General Instructions. Shipment and marking shall be as indicated below.

PAPER SUBMISSION: **The paper copy is the official copy for recording timely receipt of proposals.**

SUBMISSION OF PROPOSALS BY FACSIMILE OR E-MAIL IS **NOT** ACCEPTABLE.

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:
"**RFP NO. NIH-NIAID-DMID-08-05**
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. PAPER COPIES and CD-Rom to:

If Hand Delivery or Express Service	**If using U.S. Postal Service**
Gehmelle Johnson, Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, Maryland 20817	Gehmelle Johnson, Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address. The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

C. NUMBER OF COPIES:

TOTAL PAGE COUNT DOES NOT INCLUDE: Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section.

PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES.

FORMATTING AND LAYOUT: Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).

Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

CREATING AND NAMING ELECTRONIC FILES:

1. A separate CD should be submitted for the Technical Proposal and Business Proposal information. *Offerors who submit both Technical and Business Proposals on the same CD will be required to resubmit them on separate CDs.*

2. It is preferred that the Technical Proposal be submitted as *one electronic file document*.

   Note: if multiple files are submitted for either proposal, please include the name of the section in the file name.

   EXAMPLE: XYX Company-08-05-Technical-Approach-3-6-07

3. CDs should be named using the following format:

   Technical Proposal: ***Company name-RFP number-technical-date***
   Business Proposal: ***Company name-RFP number-business-date***

THE NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS REQUIRED OF EACH PART OF YOUR PROPOSAL ARE AS SPECIFIED BELOW.

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS EXACTLY THE SAME.

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Six (6) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	Not to Exceed 200 pages (inclusive of all Attachments and Appendices)
Business Proposal	PAPER **One (1) unbound SIGNED ORIGINAL.** **Two (2) unbound COPIES** **ELECTRONIC FILES ON CD** **Two (2) Compact Disks containing an electronic copy of the Business Proposal**	**N/A**
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	N/A

Attachment 1

ATTACHMENT 2
PROPOSAL INTENT RESPONSE SHEET
RFP NIH-NIAID-DMID-08-05
RFP Title: NIAID Division of Microbiology & Infectious Disease: Regulatory Affairs Support

Please review the attached Request for Proposal. Furnish the information requested below and return this Proposal Intent Response Sheet by mail, facsimile, or e-mail to Gehmelle Johnson no later than July 30, 2007. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING

REASONS FOR NOT SUBMITTING:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FACSIMILE OR E-MAIL TO:
Gehmelle L. Johnson, Contract Specialist
OA, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612
RFP-NIH-NIAID-DMID-08-05
Facsimile: (301) 480-4675
Email: gjohnson@niaid.nih.gov

Attachment 2

ATTACHMENT 3
STATEMENT OF WORK
NIAID DIVISION OF MICROBIOLOGY AND INFECTIOUS DISEASES:
REGULATORY AFFAIRS SUPPORT
RFP NIH-NIAID-DMID-08-05

BACKGROUND AND INTRODUCTION

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), strives to understand, treat and ultimately prevent the myriad of infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents other than Human Immunodeficiency Virus. This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics, which is funded through a variety of research grants and contracts.

Developing and testing new vaccines and therapies have historically been a major focus of the research supported by the DMID. Much of this research is devoted to addressing critical public health needs, such as those related to emerging and re-emerging infectious diseases (e.g., avian influenza and West Nile Virus), as well as those supporting the evaluation of the safety and efficacy of vaccine and therapeutic candidates against potential agents of bioterrorism, including NIAID priority biodefense pathogens (http://www3.niaid.nih.gov/Biodefense/bandc_priority.htm). In order to ensure that the development, testing and manufacture of products evaluated under DMID-supported clinical research are executed with a rigor that will support licensure by the Food and Drug Administration (FDA), DMID supports an infrastructure to provide regulatory assistance in the development and testing of these products.

Currently, DMID sponsors approximately 100 Investigational New Drug Applications (INDs) or Master Files (MFs) which span more than 200 clinical trials. This includes both multicenter trials and single center studies, and encompasses Phase 1, 2, and 3 clinical trials performed at both domestic and foreign sites. DMID files approximately 10-20 new INDs each year, and in this capacity, serves as the official IND sponsor and liaisons with the FDA with respect to all regulatory requirements. Currently, the DMID IND portfolio is comprised of approximately 75% vaccine and other biologic INDs, 20% drug INDs, and 5% MFs. In addition, it is anticipated that Investigational Device Exemptions (IDEs) will be required during the contract period of performance.

In August 2000, NIAID awarded a seven-year contract to Fisher BioServices Incorporated (N01-AI-05413) to carry out a wide variety of regulatory support functions and to maintain a clinical specimen and clinical agent repository. This contract provides scientific, regulatory, technical, project management, and administrative assistance for a broad spectrum of regulatory activities in support of DMID clinical research activities. Clinical specimen and clinical agent repository support services are currently being recompeted through a separate contract solicitation.

SCOPE

The Contractor shall provide regulatory expertise and technical and administrative support for DMID's clinical research programs. The scope of activities to be performed includes review, preparation and submission of regulatory documents, reports and other agreements; design and conduct of regulatory educational and training activities; and the provision of specialized expertise and regulatory audits.

All regulatory activities are coordinated through the DMID Office of Regulatory Affairs (ORA). In addition, the Contractor shall collaborate and coordinate with the DMID Clinical Agent and Specimen Repository (CASR) contractor, the DMID Clinical Trials Management (CTM) contractor, the DMID Statistical and Data Coordinating Center (SDCC) contractor**,** and other DMID-supported contractors and grantees involved in the conduct of clinical research.

TECHNICAL REQUIREMENTS

Independently and not as an agent of the Government, the Contractor shall furnish all services, qualified personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the work set forth below.

1. REVIEW, PREPARATION, AND SUBMISSION OF REGULATORY DOCUMENTS, REPORTS AND OTHER AGREEMENTS

A. Regulatory Submissions

Provide technical and administrative assistance in the preparation, review, assembly, archiving, distribution and tracking of DMID-sponsored pre-IND briefing documents, IND, IDE, MF, or equivalent documents, and subsequent supplemental submissions (e.g., amendments) to regulatory authorities.

1) Review regulatory requirements for specific study products and review clinical and non-clinical documents for regulatory compliance and adequacy in support of DMID INDs (reference U.S. regulation: 21CFR312), IDEs (reference U.S. regulation: 21CFR812), MFs (reference U.S. regulation: 21CFR314) (http://www.gpoaccess.gov/cfr/index.html) and other regulatory submissions in accordance with International Conference on Harmonization (ICH) guidelines (http://www.ich.org/cache/compo/276-254-1.html). Provide to the Project Officer written comments regarding recommended modifications and revisions to these regulatory documents within the time frame specified by the Project Officer. Documents include:

a. Transmittal memoranda;
b. Introductory Statements and General Investigational Plans;
c. Investigator Brochures (IBs);
d. Clinical protocols;
e. Informed consent forms;
f. Institutional Review Board (IRB) approval letters;
g. Completed FDA 1572 forms;
h. Curricula vitae of investigators;

i. Chemistry, Manufacture, and Control (CMC) information/design and manufacturing for devices;
j. Pharmacology and toxicology information;
k. Previous human experience information;
l. Annual IND, IDE and MF Reports;
m. Safety reports;
n. Responses to FDA comments; and
o. Other non-clinical testing and production protocols and reports.

2) Prepare and/or update Investigator Brochures or report of prior investigations of device in accordance with U.S. regulation 21 CFR 312.23 (a) (5) or 21 CFR 812.27 (http://www.gpoaccess.gov/cfr/index.html) for products made under contract for DMID using results of pre-clinical and clinical testing from reports, reprints and other data provided by investigators and/or pharmaceutical companies. Prepare environmental assessment exemption statements in accordance with U.S. regulation 21 CFR 25.31 (http://www.gpoaccess.gov/cfr/index.html). Provide draft documents to the Project Officer for review and approval within 5 business days of receipt of data, revise documents in accordance with Project Officer comments, and submit final IBs and environmental assessment exemption statements within 5 business days of receipt of Project Officer comments.

3) Assemble and provide draft IND, IDE, MF or other regulatory submissions, including FDA Form 1571 and transmittal memoranda for review, approval, and signature by the Project Officer. Ensure that submissions are complete and compliant with U.S. Federal and international regulations and guidelines. Provide hard copies of approved and signed submissions within 5 business days of receipt of all regulatory documents for distribution to the FDA and DMID.

4) Deliver the appropriate number of copies of IND, IDE, MF or other regulatory submissions to the FDA and obtain a stamp receipt for archives. Deliver hard copies of all FDA submissions to the Project Officer the same day the submission is delivered to FDA. Provide addressed envelopes for the distribution of transmittal memoranda to individuals designated by the Project Officer.

5) Assist in the preparation of responses to requests for information from regulatory authorities relating to IND, IDE, MF, or other regulatory applications held by DMID. Requests for information cover a broad range of issues, including protocol design, clinical monitoring, safety and adverse event reporting, CMC information, and stability data.

6) Prepare IND, IDE, and MF Annual Reports to include narrative analyses and tabular summaries of all results of DMID-supported clinical trials in accordance with U.S. regulation 21 CFR 312.33 or 21 CFR 812.150 (http://www.gpoaccess.gov/cfr/index.html), using information provided by the investigator or the data coordinating center for the clinical trial. Provide Draft Annual Reports to the Project Officer for review and approval within 5 business days of receiving information from the investigator or data coordinating center, revise reports in accordance with Project Officer comments and submit Final Annual Reports within 5 business days of receipt of Project Officer comments.

7) Provide cost efficient courier service for same day transfer of documents between DMID and the Contractor. Provide hand-carry delivery service for transmittal of documents from DMID to the FDA. Conduct mailings to study sites and product manufacturers. These mailings consist of copies of transmittal memoranda for IND submissions, requests for IND, IDE, or MF Annual Report information, and general correspondence.

B. FDA Meetings, Teleconferences and Correspondence

1) Assist in the preparation and distribution of formal written requests for pre-IND, pre-IDE and other meetings and teleconferences with the FDA. Provide draft written requests to the Project Officer for review and approval within 3 business days of notification of FDA meetings/teleconferences to be scheduled. Revise documents in accordance with Project Officer comments, and submit final written requests within 2 business days of receipt of Project Officer comments.

2) Assist in the preparation and distribution of pre-IND and pre-IDE briefing packets to FDA and DMID staff, clinical investigators and product manufacturers. Provide draft pre-IND and pre-IDE briefing packets to the Project Officer for review and approval within 10 business days of receipt of request. Revise documents in accordance with Project Officer comments, and submit final pre-IND and pre-IDE briefing packets within 10 business days of receipt of Project Officer comments.

3) Provide logistical support for meetings and teleconferences among DMID staff, clinical investigators and product manufacturers in preparation for meetings and teleconferences with the FDA regarding pre- and post-IND, MF and IDE submissions.

4) Attend and prepare detailed summaries of discussions, decisions and action items resulting from meetings and teleconferences with the FDA or other regulatory authorities. Provide draft summaries to the Project Officer for review and approval within 2 business days of each meeting/teleconference. Revise documents in accordance with Project Officer comments, and submit final summaries to Project Officer within 2 business days of receipt of Project Officer comments.

C. Regulatory Affairs Tracking and Reporting

1) Collect, track and archive all correspondence with the FDA and other regulatory authorities, including formal requests for meetings, pre-IND and pre-IDE briefing documents, FDA comments and requests for information, requests for inactivation or withdrawal of an IND, IDE or MF, FDA acknowledgement letters for inactivation and withdrawal, and stamped receipts for submission.

2) Track the anniversary dates of original and subsequent regulatory submissions. Provide written notification to the Project Officer no later than 60 days prior to due date for the submission of Annual Reports.

3) Maintain and track contact information of the DMID staff, FDA staff, clinical investigators, product manufacturers, and others for distribution of Transmittal Memoranda for regulatory submissions.

4) Provide on-site staff assistance at the DMID offices to update the DMID Regulatory Management Database System, file hard copies of IND, IDE, MF, and other regulatory documents, and maintain on-site document control of the movement of regulatory documents between DMID and the Contractor.

5) Develop and maintain, for each regulatory file, an index of IND, IDE and MF submissions, as well as Clinical Trial Agreements, including date, serial number, subject, and transmittal memoranda in a format defined by the Project Officer. Ensure that updated hard copies of each index are available on site at DMID for the review of the Project Officer. Update and submit copies of this index to the Project Officer on a monthly basis or more frequently upon request by the Project Officer.

6) Develop and maintain a system for filing, tracking and reporting on agreements to formalize DMID's relationship with product manufacturers, including Collaborative Research and Development Agreements (CRADAs), protocol-specific Clinical Trial Agreements (CTAs), Material Transfer Agreements (MTAs), Clinical Material Supply Agreements and Screening Agreements.

7) Assist the Project Officer in the preparation of responses to requests from Congress, the Department of Health and Human Services (DHHS), the NIH, and the Office of the DMID Director on regulatory matters relating to DMID-sponsored clinical trial activities.

8) Provide a monthly activity report to the Project Officer to summarize regulatory activities, including:
   - Number of pre-IND and pre-IDE briefing documents prepared
   - Number of Original INDs and IDEs submitted
   - Number of Master Files submitted
   - Number of international regulatory filings
   - Number and type of Supplements submitted
   - Number of Annual Report submitted
   - Pending Submissions
   - Number of INDs, IDEs, and MFs inactivated or withdrawn

2. REGULATORY EDUCATIONAL AND TRAINING ACTIVITIES

A. Design and conduct educational and training activities for DMID staff and DMID-supported investigators and clinical site staff utilizing any or all of the following mechanisms: webcasts, workshops, lectures, and written training guides. Topics for educational and training activities include compliance with Good Manufacturing Practices (GMP), compliance with Good Laboratory Practices (GLP), and specific regulations and guidelines for the conduct of clinical research at domestic and international sites. These activities include participating in regular meetings and teleconferences for DMID-funded clinical research networks, organized by the DMID CTM contractor, to provide general regulatory training as well as protocol specific regulatory training to clinical site personnel.

Written notification of the topic(s), audience and time frame for educational and training activities to be developed and conducted by the Contractor will be provided by the Project Officer. Within 10 business days following receipt of such written notification, submit, for Project Officer review and approval, a Draft

Educational/Training Plan outlining: the proposed mechanism for conducting the educational/training activity; a description of the content to be presented; proposed presenters; educational/training materials and references to be provided; and a written evaluation of the educational/training activity to be completed by the participants. Within 3 business days of receipt of Project Officer comments, submit the Final Educational/Training Plan. All educational and training activities must be approved in writing by the Project Officer in advance of execution.

B. Provide all necessary logistical support for regulatory educational and training activities, including: procurement of the site and/or arrangements for web-based mechanisms; rental of audiovisual equipment; registration of participants; on-site logistical support; and distribution of agendas and training materials.

C. Conduct and assess the results of participant evaluation of educational/training activities and provide summaries of the evaluations, including recommendations for improvements and modifications for future educational/training activities, to the Project Officer within 10 business days of completion of the educational activity.

3. SPECIALIZED EXPERTISE AND REGULATORY AUDITS

A. Specialized Expertise

1) Provide specialized expertise to assist in meeting the overall goals of moving investigational products through the regulatory pathway toward licensure. Areas of expertise include non-U.S. regulatory requirements and guidelines, assay development and validation, GLP, GMP, pharmacology, product formulation, statistical analysis for non-clinical studies, and toxicology.

2) Provide regulatory consultation, templates and other guidance to DMID staff and contractors. This includes consultation on pre-clinical product development requirements, requirements for product production, and filing and maintaining investigator-sponsored INDs, IDEs and MFs.

3) Update and advise the Project Officer of changes in U.S. Federal and international regulations and guidelines that may impact the DMID clinical research program.

B. Regulatory Audits

1) Provide qualified persons to perform regulatory audits in support of DMID product development activities. This includes pre- and post-award site visits to inspect and evaluate facilities for GLP and GMP compliance and audits of laboratories performing clinical assays for DMID-sponsored clinical research programs.

2) Coordinate and arrange for pre-audit meetings and teleconferences with auditors, the Project Officer and other DMID staff to determine objectives, expectations, and timelines. Distribute read ahead materials for the Project Officer, other DMID staff, and auditors at least 3 business days prior to scheduled meetings and teleconferences. Provide summaries of all pre-audit teleconferences and meetings within 3 business days of meeting to meeting and teleconference participants.

3) Review auditor reports for completeness prior to submission to the Project Officer, coordinate the provision and communication of audit report comments between the auditors and the Project Officer, and distribute final copies of audit reports to recipients designated by the Project Officer.

4) Track the number of audits and auditors used by date, site, and DMID project. Provide a monthly report to the Project Officer, listing number and location of audits conducted, auditors used, number of audit reports received, and calendar of scheduled audits.

4. ELECTRONIC INFORMATION SYSTEMS, DATA MANAGEMENT, AND SYSTEM SECURITY

A. DMID Regulatory Management Database System

1) Maintain and operate the existing DMID Regulatory Management Database System, known as the Human Subject Research Oversight and Accountability Database (HSROAD). Provide technical support and equipment to maintain the following system features:

a. Archiving, tracking, and coding of all regulatory submissions and correspondence filed with regulatory authorities, including formal requests for meetings, pre-IND briefing documents, FDA comments and requests for information, requests for inactivation or withdrawal of an IND, IDE or MF, FDA acknowledgement letters for inactivation and withdrawal, and stamped receipts for submission

b. Generation of integrated reports to sort data by:

- IND, IDE, or MF number
- IND, IDE, or MF Serial submission number
- Type of submission
- Protocol number and version
- IND, IDE, or MF status (active, inactive, clinical hold)
- IND, IDE, or MF anniversary date
- DMID Regulatory Affairs Specialist (RAS)assignment

c. An operational back-up system to ensure that archived materials are protected and preserved in the event of fire, flooding, or other catastrophic event.

d. Compatibility with information systems used by DMID and DMID clinical research contractors to ensure accessibility of data, including DMID-supplied software components or eXtensible Markup Language (XML) schemas in applications, where needed, to affect specific types of transactions, Graphical User Interface (GUI), and other software-based tasks that interact with DMID-owned databases.

2) Provide programming and IT user support for use of DMID Regulatory Management Database System, including:

a. Staff to establish, maintain, operate and enhance existing and new functions and modules for the DMID Regulatory Management Database System.

b. Development and implementation of on-going training in the use of the DMID Regulatory Management Database System for DMID staff and other individuals approved by the Project Officer such as clinical investigators or other contractors.

3) Investigate new and improved technologies to enhance the efficiency and ease of use of HSROAD. Within 90 business days of the effective date of the contract, provide an assessment and written recommendations to the Project Officer for modifications and improvements to HSROAD, including a breakdown of the costs associated with all recommended modifications and improvements. Upon written approval from the Project Officer, implement system modifications and improvements within the timeline specified by the Project Officer depending upon the extent of such modifications and improvements. All plans for any software development shall be submitted to the Project Officer and the Contracting Officer for review and approval prior to implementation.

4) Investigate and maintain on an ongoing basis current information on FDA requirements for electronic submission of regulatory documents. It is anticipated that during the life of the contract, DMID will transition from paper submission of regulatory documents to full or partial electronic submission. Within 60 business days following written notification by the Project Officer, provide an implementation plan for transition to electronic submission, including strategies for developing exchange guidelines and a set of platform technology standards to achieve compatibility and accessibility of data in accordance to FDA requirements. All plans for any software development shall be submitted to the Project Officer and the Contracting Officer for review and approval prior to implementation.

B. Data Management

1) Maintain and operate the DMID Regulatory Management Database System to ensure the capacity to access, receive, transmit, upload and download specific data from other DMID-owned data management systems. This includes compatibility with multiple and varied hardware and software systems in order to receive, scan and transmit electronic messages, documents, data files, query forms and reports to/from DMID, the Contractor and the other DMID clinical research contractors.

2) Ensure the effective and efficient coordination of data to complete specified regulatory functions in collaboration with the DMID Clinical Agent and Specimen Repository (CASR) contractor, the DMID Clinical Trials Management (CTM) contractor, the DMID Statistical and Data Coordinating Center (SDCC) contractor, and other DMID-supported contractors**.** These regulatory functions include:

a. Track and provide regulatory status information for each DMID IND and IDE to the CASR to determine if clinical agents may be shipped to the CASR from suppliers under IND or IDE.

b. Collect, track and report on the receipt of essential regulatory documents in accordance with 21CFR (http://www.gpoaccess.gov/cfr/index.html) and ICH guidelines (http://www.ich.org/cache/compo/276-254-1.html) for each DMID IND and IDE to determine if clinical agents may be shipped to the clinical sites.
c. Prepare IND, IDE and MF Annual Reports and other study reports by obtaining data from the SDCC or other DMID-approved coordinating centers.

3) Develop and implement validation processes and procedures to ensure the accuracy, completeness and integrity of data in DMID Regulatory Management Database System. Within 30 business days of the effective date of the contract, submit a Draft Data Validation Plan for validation processes and procedures for review by the Project Officer. Modify the plan in accordance Project Officer comments, and submit the Final Data Validation Plan to the Project Officer within 10 business days of receipt of Project Officer comments.

4) Provide monthly Data Validation Reports to the Project Officer to include information on data integrity, completeness and accuracy, including identification of errors and problems, recommendations for correcting errors and resolving problems, and the plans for the implementation of corrective actions approved by the Project Officer.

C. System Security

Develop and implement an Information Security Plan which meets NIH Information Security requirements and complies with the HHS Secure One-Information Security Program Policy (http://intranet.hhs.gov/infosec/policies_guides.html). Within 20 business days of the effective date of the contract, submit, for Project Officer review and approval, Information Security Plan. References for system security information and guidance are located in Section H of the contract at the end of the Article entitled "Information Security." Requirements for information security include the following:

1) A System's Security Plan (SSP) which minimally shall include the Risk Analysis (RA) and the Continuity of Operations Plan (COOP – also known as the Contingency Plan).

2) The preparation and submission of an annual Information System Security Plan (ISSP), following the instructions in the HHS Secure One Policy (http://intranet.hhs.gov/infosec/about.html) for review and approval by the Project Officer and the NIAID Information System Security Officer (ISSO).

3) A log or record of the results from testing the COOP, any existing plans and progress reports for implementing additional security safeguards and controls, and the system access authorization list. The profile shall be kept up-to-date for review and potential inspection upon demand by NIH/DHHS authorized agents. Upon request, copies of specified profile documents shall be presented to the NIH/DHHS for its own system's security reporting requirements.

4) The preparation and submission, for Project Officer approval, of a RA following the guidance given in the HHS Secure One Policy. The RA is to be maintained and updated every three years, or in advance of implementing major system modifications or enhancements.

5) The development and maintenance of an up-to-date COOP following the guidance in the HHS Secure One Policy. At a minimum, the COOP shall cover emergency operations, backup operations, and recovery plans to assure continuous operations of the system's facility. COOP testing shall be conducted and the results recorded at least every six months.

6) Plans, procedures and a recommended schedule and budget for implementation of security safeguards required to satisfy the anticipated conditions of acquiring data. This includes data integrity and security during electronic transmission or during transit.

5. QUALITY ASSURANCE/QUALITY CONTROL (QA/QC)

A. Develop and implement a Quality Assurance/Quality Control plan to standardize contract processes to ensure that the conduct of all activities complies with domestic and non-domestic regulatory regulations and meets the requirements of the contract. Specifically, develop and implement a QA/QC Plan including the following tasks:

1) Provide a list of Standard Operating Procedures (SOPs) for all operations outlined in the Statement of Work within 30 business days of the effective date of the contract and ensure that copies of SOPs are available for review by the Project Officer upon request.

2) Maintain version control of all SOPs (both QA and technical) to ensure that the current SOP versions are utilized and superseded versions are removed from circulation.

3) Review and approve all SOPs prior to distribution and use.

4) Ensure that annual trainings on SOPs are conducted and documented for Contractor personnel.

5) Maintain a list of the validation status of equipment and computer software.

6) Ensure that access to computerized systems is secure and back-ups occur on a daily basis.

7) Develop and implement a record retention and storage plan.

8) Ensure the accuracy and integrity of tracking of regulatory support activities.

B. Within 15 business days of the contract effective date, submit a Draft QA/QC Plan for Project Officer review and approval. The Project Officer will provide comments on the Draft QA/ Plan within 14 business days of receipt. Submit the Final QA/QC Plan, which incorporates revisions based on Project Officer comments,10 business days after receipt of Project Officer comments. The QA/QC Plan shall include SOPs for

establishing and maintaining the QA/QC processes and approaches/methods to document, identify the source(s) for, and address problems as they occur. Any proposed modifications to the QA/QC Plan, including SOPs, shall be submitted to the Project Officer for review and approval prior to implementation.

C. Ensure that appropriate Contractor and subcontractor staff and all necessary information/documentation are available for independent paper audits of Contractor and subcontractor facilities as needed to evaluate compliance with domestic and non-domestic laws and regulations, DMID policy, and the terms of the contract.

6. PROJECT MANAGEMENT

A. Overall Project Management

1) Provide for the overall management, integration and coordination of all contract activities, including the management and coordination of activities carried out in collaboration with other DMID contractors and the management of functions and activities carried out by any subcontractors.

2) Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, management and timely completion of all projects carried out under this contract and effective communications with the Project Officer and the Contracting Officer.

3) Designate a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors.

4) Provide personnel to coordinate contract specific activities and administrative staff with responsibility for financial management and financial reporting on all activities conducted by the Contractor and subcontractors.

5) Ensure that the Contractor and any proposed subcontractors will safeguard confidentiality and intellectual property of data and materials provided to them by third parties or the United States Government, as well as data generated during the contract.

B. Meetings

1) *Contract Initiation Meeting*

Within 10 business days of the effective date of the contract, the Principal Investigator (PI) and other key personnel, as determined by the Principal Investigator and agreed upon by the Project Officer, shall participate in a one-day contract initiation meeting with the Project Officer, the Contracting Officer, and other key DMID staff, to be held in the Bethesda, Maryland area. The purpose of this contract initiation meeting is to orient the Contractor to NIAID contract procedures and address issues, questions, processes and timelines for the initiation of contract activities.

2) *Weekly Progress Meetings/Teleconferences*

The PI, key Contractor personnel and, when appropriate, senior subcontractor staff, as designated by the PI, shall participate in weekly meetings and/or teleconferences with the Project Officer and other relevant DMID staff to discuss the status of ongoing regulatory activities, identify and develop approaches to resolving problems encountered with respect to regulatory responsibilities, and review plans for upcoming projects. The Contractor shall be prepare and submit meeting agendas and background materials to the Project Officer for review and approval no less than 2 business days in advance of the meeting or teleconference, distribute meeting materials to meeting or teleconference participants within 1 business days in advance of the meeting or teleconference, and prepare and submit meeting summaries to the Project Officer and participants within 3 business days after each meeting or teleconference.

3) *Bi-Weekly Meetings with DMID Office of Regulatory Affairs (ORA)*

The PI, key Contractor personnel and, when appropriate, senior subcontractor staff, as designated by the PI and the Project Officer, shall participate in bi-weekly meetings with the Project Officer and other DMID ORA staff to discuss ongoing regulatory activities and future needs/plans. The Contractor shall be prepare and submit meeting agendas and background materials to the Project Officer for review and approval no less than 3 business days in advance of the meeting or teleconference, distribute meeting materials to meeting or teleconference participants within 2 business days in advance of the meeting or teleconference, and prepare and submit meeting summaries to the Project Officer and participants within 2 business days after each meeting or teleconference.

4) *Annual Meetings*

The PI and key staff of the Contractor and, where appropriate, senior subcontractor staff, shall participate in annual 2-day meetings, to be held in the Bethesda, Maryland area, to address ongoing regulatory issues, requirements and needs and to discuss plans for the upcoming year

7. INITIAL AND FINAL TRANSITION

A. Initial Transition

1) In the event of a new contractor, provide for the efficient, orderly and safe transition of contract activities, data systems, documents and other information from the incumbent contractor without loss of time or interruption to the conduct of ongoing clinical trials and clinical trials in development. The following shall be transferred to the Contractor:

   a. Electronic and hard copies of regulatory files submitted to domestic and non-domestic regulatory authorities including INDs, IDEs, and MFs
   b. Correspondence files with the FDA, product manufacturers, clinical research sites, and DMID
   c. Files for DMID CTAs, MTAs and other agreements
   d. HSROAD, the DMID Regulatory Management Database System

e. Government-furnished property
f. Audit and Site Visit Reports

2) Draft Initial Transition Plan: Within 5 business days of the contract effective date, the Project Officer will provide to the Contractor a copy of the Final Transition Plan from the incumbent contractor. Based on this Final Transition Plan and the requirements set forth in the Statement of Work, the Contractor shall develop and submit, for Project Officer review and approval and within15 business days of the contract effective date, a Draft Initial Transition Plan specifying proposed timelines to ensure an efficient, safe and orderly transition of contract data, systems and activities, as well as the staff to be assigned to implement the initial transition with defined roles and responsibilities.

3) *Final Initial Transition Plan*: Revise the Draft Initial Transition Plan as necessary to address Project Officer comments and submit the Final Initial Transition Plan within 10 business days of receipt of Project Officer comments.

4) Provide training for all Contractor staff associated with the transfer and operation of these activities.

5) Implement the Final Initial Transition Plan, as approved to the Project Officer, including all tasks associated with the relocation effort from the incumbent contractor. The Initial Transition shall be completed within 30 business days of the contract effective date, and the Contractor shall submit to the Project Officer an Initial Transition Report summarizing all transition activities within15 business days of initial transition completion.

B. Final Transition

1) In the event of a new contractor, provide for the efficient, orderly and safe transition of contract activities, data systems, documents and other information from to the successor contractor without loss of time or interruption to the conduct of ongoing clinical trials and clinical trials in development. The following will be transferred by the Contractor:

a. Electronic and hard copies of regulatory files submitted to domestic and non-domestic regulatory authorities including INDs, IDEs, and MFs
b. Correspondence files with the FDA, product manufacturers, clinical research sites, and DMID
c. Files for DMID CTAs, MTAs and other agreements
d. HSROAD, the DMID Regulatory Management Database System, and any modifications to HSROAD made in the performance of the contract.
e. Government-furnished property
f. Audit and Site Visit Reports

2) *Draft Final Transition Plan*: One year prior to the completion date of the contract, submit, for Project Officer review and approval, a Draft Final Transition Plan specifying proposed timelines to ensure an efficient, safe and orderly transition of contract data, systems and activities, as well as the staff to be assigned by the Contractor to implement the initial transition with defined roles

and responsibilities. This includes removal of all government information from electronic information systems maintained by the Contractor.

3) *Final Transition Plan*: Revise the Draft Final Transition Plan as necessary to address Project Officer comments and submit the Final Transition Plan 10 months prior to the completion date of the contract.

4) Implement the Final Transition Plan, as approved to the Project Officer, including all tasks associated with the relocation effort from the incumbent contractor. The Final Transition shall be completed within 45 business days prior to the completion date of the contract, and the Contractor shall submit to the Project Officer a Final Transition Report summarizing all transition activities 20 business days prior to the completion date of the contract.

ATTACHMENT 4
REPORTING REQUIREMENTS AND DELIVERABLES

A. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract:

These reports shall address any problems encountered during the period, show the effect of the problem on the project or budget, propose a solution or action taken to resolve problem, and summarize action taken to alleviate the reoccurrence of the problem. They are subject to technical inspection and requests for clarification by the Project Officer.

All reports shall be submitted in an electronic form compatible with the current DMID supported software (Microsoft Word™ and Microsoft Excel™) and approved by the Project Officer. Electronic files shall be sent by e-mail or on computer discs (CD) by U.S. mail or courier service. In addition, two (2) hard copies of all reports shall be submitted to the Project Officer and one (1) hard copy shall be submitted to the Contracting Officer, except in the case of the Annual Technical Progress Reports, Final Report and the Initial and Final Transition reports where three (3) hard copies of these reports shall be submitted to the Project Officer.

Reports shall include the Contract Title and number, title of report, period of performance being reported, and date of submission.

1. Monthly Progress Report

The Monthly Progress Report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. The Report is due on/before the 15th of the month following each reporting period and must include the following sections:

a. Introduction: A section covering the purpose and scope of the contract effort.
b. Progress report: A section describing overall progress for each task or segment of work listed in the Statement of Work on which effort was expended during the reporting period. For example, the report shall include summaries or charts/graphs/tables on regulatory status or change of status of DMID held INDs, IDEs, MFs and protocols, original IND/IDE/MF submission, pre-IND/IDE/MF submissions, annual reports and final IND/IDE/MF reports filed, Data Validation Reports, filings made to all INDs, IDEs and MFs, outstanding regulatory documents or filings, consultants or subcontracts signed and active, number of audits conducted, training activities for Contractor staff, DMID staff, and clinical study site staff, and tracking changes/enhancements in electronic systems.
c. Personnel changes: A section covering any changes in personnel.
d. Problems and solutions: A section describing technical or performance problems encountered and corrective action taken. An explanation of any differences between planned and actual progress shall be included.

e. Financial report: A section describing the financial status of the contract (total costs by element).
f. Maintenance of facilities, supplies and equipment: A section describing problems encountered and corrective action taken since the last monthly report.

A Monthly Progress Report shall not be due when the Semiannual Progress Report and Annual Progress Report are due.

2. Semiannual Progress Report

The Semiannual Progress Report shall include a summation of previously submitted monthly reports. The initial Semiannual Progress report shall be submitted for the first full six (6) months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six (6) full calendar months and the report is due on/before the 15th of the month following each reporting period. This report shall include all of the sections provided in the Monthly Progress Report and an additional section to address the anticipated work plan for the next (6) six months.

A Semiannual Progress Report shall not be due when the Annual Progress Report is due.

3. Annual Technical Progress Report

Within thirty (30) days following the anniversary date of the contract, the Contractor shall submit an Annual Technical Progress Report. This report shall include a summation of the results of the entire contract work for the period covered. This report shall include all of the sections provided in the Monthly Progress Report and an additional section to summarize all work conducted during the reporting period and a section to address the anticipated work plan for the coming year.

An Annual Technical Progress Report will not be required for the period when the Final Report is due.

4. Draft Final Report

The Contractor shall provide to the Project Office and the Contracting Officer the Draft Final Report one hundred-twenty (120) business days prior to the expiration date of the contract. The Project Officer will review the Draft Final Report and provide the Contractor with comments within thirty (30) business days after receipt. The Draft Final Report shall be corrected by the Contractor, if necessary.

5. Final Report

Within sixty (60) business days of the expiration date of the contract, the Contractor shall submit a comprehensive Final Report. This report shall consist of the work performed and results obtained for the entire contract period of performance as stated in Section F of this contract. This report shall be in sufficient detail to describe comprehensively the results achieved.

If the Contractor becomes unable to deliver the reports specified above within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall provide the Contracting Officer

with immediate written notice of anticipated delay, the reason for the delay, and the expected date of delivery for the report.

B. Technical Reports Delivery Schedule

Satisfactory performance of the contract is defined as satisfactorily performing the statement of work and delivering the following items.

Progress Reports

Item	Type of Report	Initial Report Due	Recipient & Number of Hard & Electronic Copies	Subsequent Reports Due
1.	**Monthly Progress Report**	15th of the month following the first reporting period consisting of the first full month of performance plus any fractional part of the initial month.	2 hard copies & 1 electronic copy to PO 1 hard copy to CO	The 15th of the month following each reporting period. A Monthly Progress Report shall not be due when the Semiannual Progress Report and Annual Progress Report are due.
2.	**Semiannual Progress Report**	15th of the month following the first reporting period consisting of the first full 6 months of performance plus any fractional part of the initial month	2 hard copies and 1 electronic copy to PO 1 hard copy to CO	Semiannually; due on the 15th of the month following the end of each 6-month period beginning with the start of the contract. A Semiannual Progress Report will not be due when an Annual Progress Report or Final Report is due.
3.	**Annual Technical Progress Report**	Within 30 days after the anniversary date of contract	3 hard copies and 1 electronic copy to PO 1 hard copy and 1	Annually; submitted within 30 days after the anniversary date. An Annual Progress Report is not due when a Final Report is due.

			electronic copy to CO	
4.	**Draft Final Report**	120 business days prior to the expiration date of contract	2 hard copies and 1 electronic copy to PO 1 hard copy and 1 electronic copy to CO	
5.	**Final Report**	Within 60 business days of the expiration date of the contract.	3 hard copies and 1 electronic copy to PO 1 hard copy and 1 electronic copy to CO	

C. Other Reports/Deliverables

1. Source Code and Object Code

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

Other Reports

2. REPORTING REQUIREMENTS AND DELIVERABLES

Offeror: In addition to the reporting which has been described herein, describe additional reports, other than progress reports, which will be delivered to the Government during performance of the contract.

Item	Type of Report	Initial Report Due	Recipient & Number of Hard & Electronic Copies	Subsequent Reports Due
1.	**Initial Transition Report**	Complete initial transition within 30 business days of contract effective date and submit Initial	3 hard Copies to PO 1 hard Copy to CO Electronic copies to PO	

		Transition Report within 15 business days of initial transition completion	and CO	
2.	**Final Transition Report**	Complete final transition within 45 business days prior to completion date of contract and submit the Final Transition Report 20 business days prior to the completion date of the contract	3 hard copies and 1 electronic copy to PO 1 hard copy and 1 electronic copy to CO	

D. ARTICLE F. 1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

The items specified below as described in SECTION C, will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract:

Deliverables

Offeror: Provide a description of all items to be delivered to the Government during performance of the contract, include all work product, end products, and deliverables.

Item	Type of Deliverable	SOW Reference	Due	Recipient	Subsequent Deliverables Due
1.	Written comments and recommendations on regulatory documents reviewed for compliance with domestic and non-domestic regulations	Item 1.A.1	Upon review of regulatory documents within timeframe to be determined by Project Officer based on type and length of document	Project Officer	
2.	Draft Investigator Brochures or report of prior investigations of	Item 1.A.2	Within 5 business days of receipt of data	Project Officer	Final due within 5 business

	device in compliance with 21 CFR 312.23 (a) (5) and 21 CFR 812.27				days of receipt of Project Officer comments on draft
3.	Draft Environmental Assessment exemption statements in accordance with U.S. regulation 21 CFR 25.31	Item 1.A.2	Within 5 business days of receipt of data	Project Officer	Final due within 5 business days of receipt of Project Officer comments to draft
4.	Draft IND, IDE, MF or other regulatory submissions, including FDA Form 1571 and transmittal memoranda	Item 1.A.3	Within 5 business days of receipt of all documents to be submitted	Project Officer	
5.	Delivery of hard copies of final IND, IDE, MF or other regulatory submissions	Item 1.A.4	After receipt of Project Officer's approval	Project Officer, FDA, other appropriate regulatory authorities and individuals designated by Project Officer	
6.	Draft IND, IDE, and MF Annual Reports in accordance with U.S. regulation 21 CFR 312.33 and 21 CFR 812.150	Item 1.A.6	5 business days from receipt of data	Project Officer	Final due within 5 business days of receipt of Project Officer comments to draft
7.	Draft written requests for meetings with FDA	Item 1.B.1	Within 3 business days of notification by the Project Officer that a meeting will be scheduled	Project Officer	Final due within 2 business days of receipt of Project Officer comments to draft

8.	Draft pre-IND, pre-IDE briefing packets to FDA	Item 1.B.2	Within 10 business days of receipt of request	Project Officer	Final due within 10 business days of receipt of Project Officer comments to draft
9.	Summaries of meetings and teleconferences with the FDA or other regulatory authorities	Item 1.B.4	Within 2 business days of each meeting /teleconference	Project Officer	Final due within 2 business days of receipt of Project Officer comments to draft.
10.	Written notification of anniversary dates of original regulatory submissions	Item 1.C.2	60 days prior to due date for the submission of the Annual Progress Report	Project Officer	
11.	Index of IND, IDE, MF submissions and Clinical Trial Agreements	Item 1.C.5	Monthly	Project Officer	
12.	Draft Educational/Training Plan	Item 2.A	Within 10 business days of receipt of written notification	Project Officer	Final due within 3 business days of receipt of Project Officer comments to draft.
13.	Evaluations and recommendations of educational/training activities	Item 2.C	Within 10 business days of completion of the educational activity	Project Officer	
14.	Preparatory materials for pre-audit teleconferences and meetings	Item 3.B.2	3 business days prior to meeting	Project Officer	
15.	Summaries of pre-audit teleconferences and meetings	Item 3.B.2	Within 3 business days of meeting	Project Officer	
16.	Final audit report	Item 3.B.3	As determined by the Project Officer	Persons designated by Project Officer	
17.	Assessment and	Item 4.A.3	Within 90	Project Officer	

	written recommendations to modifications and improvements to HSROAD		business days of the effective date of the contract	Include Contracting Officer, if software development recommended	
18.	Implementation plan for transition to electronic submission	Item 4.A.4	Within 60 business days following written notification from Project Officer	Project Officer Include Contracting Officer, if software development recommended	
19.	Draft Data Validation Plan	Item 4.B.3	Within 30 business days of the effective date of the contract	Project Officer	Final due within 10 business days of receipt of Program Officer comments to draft
20.	Information System Security Plan (ISSP)	Item 4.C.2	Within 20 business days of the effective date of the contract	Project Officer and NIAID Information System Security Officer (ISSO)	Annually
21.	Security System Profile	Item 4.C.3	Upon request	NIH/DHHS authorized agents	
22.	Risk Analysis	Item 4.C.4	Initially due with item 20 ISSP	Project Officer and NIAID Information System Security Officer (ISSO)	Every three (3) years
23.	List of Standard Operating Procedures (SOPs)	Item 5.A.1	Within 30 business days of the effective date of the contract	Project Officer	
24.	Draft QA/QC Plan	Item 5.B	Within 15 business days of the contract effective date	Project Officer	Final due 10 business days after receipt of Project Officer comments to draft
25.	Draft Initial Transition Plan	Item 7.A.2	Within 15 business days of the contract effective date	Project Officer	
20.	Final Initial Transition Plan	Item 7.A.3	Within 10 business days of the contract	Project Officer	

			effective date		
26.	Draft Final Transition Plan	Item 7.B.2	1 year prior to completion of contract	Project Officer	
27.	Final Transition Plan	Item 7.B.3	10 months prior to completion of contract	Project Officer	

E. Copies of reports shall be sent to the following addresses:

Project Officer:
National Institutes of Health, DHHS
National Institute of Allergy and Infectious Diseases
Division of Microbiology and Infectious Diseases
Office of Regulatory Affairs
6610 Rockledge Drive, Room 6035
Bethesda, MD 20892-7630

Contracting Officer:
National Institutes of Health, DHHS
National Institute of Allergy and Infectious Diseases
Office of Acquisitions, DEA
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

Information System Security Officer:
National Institutes of Health, DHHS
National Institute of Allergy and Infectious Diseases
Information System Security Officer
Office of the CIO
10401 Fernwood Road, Room 2SE04
Bethesda, MD 20892

ATTACHMENT 5
ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS
AND FORMAT FOR TECHNICAL PROPOSAL

It is strongly recommended that Offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These additional Technical Proposal instructions reflect the requirements of the RFP and provide specific instructions and formatting for the Technical Proposal. The information requested in these instructions should be used to format and prepare the Technical Proposal, and should be used as a table of contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested in this Appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, appendices and attachments, the Technical Evaluation Criteria in Section M, and the RFP as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration/coordination between the prime contractor and all proposed subcontractors, and the expected advantages of such an approach.

Offerors are reminded that the total page limitation for the entire Technical Proposal package is 200 pages inclusive of all attachments and appendices.

Pages in excess of the limit will be removed and will not be read, evaluated, or considered for review.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

I. PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
II. PROJECT OBJECTIVES (NIH FORM 1688-1)
III. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
IV. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
V. TABLE OF CONTENTS

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested limit of 3 pages)

Provide a brief description of the Technical Proposal, including:

A. A description of the activities to be performed by the offeror and those that shall be provided by all proposed subcontractors. This description should include the identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles.

B. A brief description of the facilities, equipment and other resources to be made available by the offeror and all proposed subcontractors.

SECTION 3: TECHNICAL APPROACH

A. Review, Preparation, and Submission of Regulatory Documents, Reports and Other Agreements (SOW item 1)

1) *Regulatory Submissions*: Describe proposed plans and procedures for reviewing specific study products and clinical and non-clinical documents for regulatory compliance and adequacy in support of Investigational New Drug (IND) applications, Master Files (MFs) and Investigational Device Exemptions (IDEs). Include a discussion of key features to address and common errors and deficiencies uncovered in the review of such documents, and give examples of recommendations provided by the offeror for correcting common errors and deficiencies. Also provide the number and a general description of INDs, MFs and IDEs reviewed for regulatory compliance and adequacy over the past 5 years. Include only the type of regulatory submission (i.e., IND, MF and IDE), the type of product (i.e., therapeutic, vaccine, device), and the phase of the clinical trial.

2) *Investigator Brochures (IBs) and Environmental Assessment Exemption Statements*: Describe proposed plans and procedures for preparing and updating IBs and for preparing environmental assessment exemption statements. Include a discussion of key features to address in the preparation of such documents and common problems encountered in assessing and arraying the results of pre-clinical and clinical testing. Also provide a sample table of contents for IBs and a list of IBs and environmental assessment exemption statements prepared over the past 5 years.

3) *IND, MF and IDE Annual Reports*: Describe proposed procedures for the preparation of IND, MF and IDE Annual Reports. Include a discussion of common problems encountered in preparing narrative analyses and tabular summaries based on existing clinical trial data and approaches used to resolve common problems. Also provide the number and a general description of INDs, MFs, and IDEs for which annual reports have been filed over the past 5 years. Include only the type of regulatory submission (i.e., IND, MF and IDE), the type of product (i.e., therapeutic, vaccine, device), and the phase of the clinical trial.

4) *FDA Meetings, Teleconferences and Correspondence*:

(a) Describe experience with assisting in the preparation of pre-IND/MF/IDE briefing packets for the U.S. Food and Drug Administration (FDA) and other regulatory authorities. This includes: (i) the number of such packets prepared over the past 5 years and the regulatory authorities to which such packets were submitted; (ii) a description of the specific components of such packets for which the offeror assumed primary responsibility; (iii) a discussion of the key features of the investigational product and clinical trial to be addressed in such interactions with regulatory authorities; and (iv) a discussion of

problems encountered in the preparation of such packets and the approaches taken to resolve them. Also include a sample table of contents for pre-IND/MF/IDE briefing packets.

(b) Describe experience in arranging for, attending and preparing summaries of meetings and teleconferences with the FDA and other regulatory authorities. Provide the number and dates of such meetings and teleconferences attended by the offeror over the past 5 years.

5) *Regulatory Affairs Tracking and Reporting*:

(a) Describe proposed plans and procedures to be used to: (i) index all regulatory submissions and associated correspondence/materials; (ii) track key dates for regulatory submissions, including due dates for annual reports and other action items; (iii) maintain and track contact information for each IND, MF and IDE; (iv) file and track Clinical Trials Agreements (CTAs), Material Transfer Agreements (MTAs), Clinical Material Supply Agreements and Screening Agreements; and (v) provide monthly activity reports to summarize regulatory activities.

(b) Describe experience with assisting in the preparation of responses to requests for information on regulatory activities from various sources, including Congress and the Department of Health and Human Services. Include a description of the types of information requests received over the past 5 years and the specific role of the offeror in preparing responses to such requests.

B. Regulatory Educational and Training Activities (SOW item 2)

1) Provide a complete plan for the conduct of a one-day training workshop for clinical site staff at domestic and international sites on compliance with regulatory requirements and guidelines governing research involving human subjects. This plan should include: (i) agenda and proposed format, e.g., lectures, small group working sessions; case studies, etc.; (ii) list of proposed presenters and a description of their experience and qualifications; (iii) training materials and references to be provided to workshop participants; and (iv) evaluation instrument to assess the quality and appropriateness of the training.

2) Provide a list of regulatory training activities addressing domestic and non-domestic general regulatory requirements governing clinical research as well as protocol-specific regulatory requirements .conducted by the offeror and any proposed consultants/subcontractors over the past 5 years. Include the mechanisms used (e.g., workshop, webcast, etc.), topics, audiences, agendas, and evaluation instruments. Also provide a summary of the results of participant assessments for regulatory training activities conducted, including a discussion of strengths, weaknesses and suggested improvements noted by participants, and describe modifications and improvements implemented as a result of these assessments.

3) Describe proposed procedures for providing all necessary logistical support for regulatory educational and training activities, including: procurement of site and/or arrangements for web-based mechanisms;

registration of participants; on-site logistical support; and distribution of agendas and training materials.

C. Specialized Expertise and Regulatory Audits (SOW item 3)

1) *Specialized Expertise*: Describe plans for the provision of specialized expertise in each of the following areas: (i) non-U.S. regulatory requirements and guidelines; (ii) assay development and validation; (iii) Good Laboratory Practice (GLP); (iv) Good Manufacturing Practice (GMP); (v) pharmacology and product formulation; (vi) toxicology; and (vii) statistical analysis for non-clinical studies. Include a description of the types of specialized expertise and the projects for which such expertise has been provided over the past 5 years.

2) *Regulatory Audits*: Provide a plan for performing regulatory audits in support of DMID product development activities, including pre- and post-award site visits to inspect and evaluate facilities for GLP and GMP compliance and audits of laboratories performing clinical assays. This plan should include: (i) a discussion of how services will be provided, i.e., in-house through Contractor staff and/or through the use of consultants and subcontractors; (ii) organizational experience in providing and/or overseeing the provision of such services over the past 5 years, including arranging for pre-audit meetings and teleconferences and reviewing auditor reports for completeness; and (iii) tracking and reporting on all audit activities by date, site and project. Also include a discussion of common problems encountered in the planning and conduct of regulatory audits and approaches to overcoming such problems and obstacles.

D. Electronic Information Systems, Data Management, and System Security (SOW item 4)

1) Describe organizational experience in and provide a plan for maintaining and operating database information systems. Include a description of software and hardware used by the offeror and any proposed subcontractors over the past 5 years for projects of the same or similar scope, complexity and requirements. Also include a discussion of problems that have been encountered in the maintenance, operation and security of information systems used for the same or similar purposes and the approaches implemented to resolve these problems.

2) Describe organizational experience in and provide a plan for coordinating regulatory affairs support functions with other clinical research support contractors with respect to: (i) tracking and reporting on the status of INDs, MFs, IDEs and clinical protocols; (ii) documenting receipt of essential regulatory documents for shipping of clinical agents; and (iii) obtaining clinical data for preparation of IND, MF and IDE Annual Reports to the FDA and other regulatory authorities. Include a discussion of proposed methods for achieving effective and efficient coordination, anticipated problems, and approaches to resolving anticipated problems.

3) Describe organization experience in electronic submission of regulatory documents to the FDA. Include a discussion of previous problems encountered in this area, anticipated problems associated with an expansion in the use of electronic submissions, and proposed approaches to the resolution of anticipated problems and obstacles.

4) Describe organization experience with NIH Information Security requirements and familiarity with HHS Secure One-Information Security Program Policy (http://intranet.hhs.gov/infosec/policies_guides.html). Provide a proposed plan to meet requirements for information security.

E. Quality Assurance/Quality Control (SOW item 5)

Provide a proposed Quality Assurance/Quality Control (QA/QC) Plan to standardize contract processes to ensure that the conduct of all activities complies with domestic and non-domestic regulations and requirements. The proposed QA/QC Plan should include: (i) a list of Standard Operating Procedures (SOPs) for all operations outlined in the Statement of Work, including procedures for maintaining version control of all SOPs; (iii) SOP template; (ii) plans for annual training of Contractor and subcontractor staff with respect to all operating procedures; (iii) procedures for maintenance of validation status of equipment and computer software; (iv) plans for documenting adherence to all applicable requirements; and (v) record retention and storage procedures and plans to ensure the accuracy and integrity of tracking processes for regulatory support functions.

F. Initial and Final Transition (SOW item 7)

Provide proposed plans for the initial and final transition of contract materials, databases and equipment, including approaches to ensure that there is no loss of time or interruption to the conduct of ongoing clinical trials and clinical trials in development during the transition period. Discuss the proposed staffing requirements for the initial and final transition, including number and type of personnel required, as well as proposed percent effort. Also provide proposed plans for the training of Contractor and subcontractor personnel with respect to all aspects of initial and final transition activities.

SECTION 4: PERSONNEL

Describe the training, education, expertise, qualifications, relevant experience and proposed effort for the Principal Investigator and all scientific and technical staff, including staff of the offeror and all proposed consultants and subcontractors. Limit the CVs to 2-3 pages, provide selected references for publications relevant to the scope of requirements for the contract, include relevant ongoing projects, and limit previous experience to the past 5 years.

A. Principal Investigator: Document training, education, expertise, qualifications and experience in the following areas:

1) Regulatory requirements and guidelines, both domestic and non-domestic, governing the conduct of research involving human subjects.
2) Preparation and review of clinical and non-clinical regulatory documents and requirements for specific study products for submission of INDs, MFs and IDEs to the FDA and other regulatory authorities, and preparation of narrative analyses and tabular summaries for IND, MF and IDE Annual Reports.
3) Preparation of pre-IND/MF/IDE briefing materials and participation in meetings and teleconferences with the FDA and other regulatory authorities and preparation of meeting/teleconference summaries.
4) Design and conduct of regulatory educational and training activities.

5) Management, oversight and system security for databases and information systems for tracking and reporting on regulatory activities, including coordination with other clinical research support contractors.
6) Provision of specialized expertise and regulatory audits directly or via consultants/subcontractors.
7) Working with product manufacturers on regulatory submissions and reporting, and with clinical study site personnel on adherence to regulatory requirements and guidelines.
8) Coordination, management and QA/QC for projects of similar size and complexity.

B. Other Scientific and Technical Personnel: Document the training, education, expertise, qualifications and experience of other proposed scientific and technical personnel of the offeror and all proposed consultants and subcontractors in the following areas:

1) *Regulatory affairs personnel* with respect to preparation, review and submission of regulatory documents and pre-briefing materials for the FDA and other regulatory authorities.
2) *Personnel for regulatory educational and training activities* with respect to the design, conduct and evaluation of training activities for government and clinical site staff.
3) *Specialized experts* for: non-U.S. regulatory requirements and guidelines; assay development and validation; Good Laboratory Practice (GLP); Good Manufacturing Practice (GMP); pharmacology and product formulation; toxicology; and statistical analysis of non-clinical data.
4) *Information Technology personnel* for: the maintenance and operation of existing databases, back-up systems and system security procedures; interface with other clinical research support contractors; evaluation of new and improved technologies and implementation of system upgrades/modifications; and programming and set-up of regulatory information systems and training for government staff.
5) *Technical personnel* for the collection, coding, and storage of regulatory documents, correspondence and other materials, and for the preparation of routine and ad hoc reports on the status of regulatory activities and action items.

SECTION 5: FACILITIES, EQUIPMENT AND OTHER RESOURCES

Provide the following information:

A. A description of proposed location for the prime Contractor and any proposed subcontractors, including information regarding ownership or lease of proposed facilities demonstrating availability at the initiation of the contract and for the duration of the contract period of performance.
B. A detailed description of equipment proposed for the project and its availability at the initiation of the contract and for the duration of the contract period of performance.

SECTION 6: PROJECT MANAGEMENT (SOW item 6)

A. Describe how the project will be staffed, organized and managed. Describe in detail the responsibilities and level of effort for all proposed personnel, including all proposed subcontractors, who will be assigned to the contract, and provide an administrative framework indicating clear lines of authority and responsibility for the personnel. Include a diagram of the proposed organizational/management structure for the project.

B. Describe project management systems that will be used to track activities and to keep multiple activities on time and within budget. The plan should include a description of quality control methods that will be used to ensure the effective initiation, implementation, management and oversight of contract activities.

C. Outline how the Principal Investigator will communicate and interact with the Contracting Officer and the Project Officer and how the Principal Investigator will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

D. Provide a plan for how the Contractor and any proposed subcontractors will safeguard confidentiality and intellectual property of data and materials provided to them by third parties or the United States Government, as well as data generated during the contract.

SECTION 7: ALL OTHER DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION NOT SPECIFICALLY ADDRESSED ABOVE

ATTACHMENT 6
ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

In addition to the format requirements for the business proposal that are contained in Section L of the solicitation, the information provided in this Appendix is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the statement of work, all reference material provided as appendices and attachments, the technical evaluation criteria, and, the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your business proposal. Offerors should consider and include the information requested in this appendix, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVERSHEET (use form NIH 2043 identified in Section J)

SECTION 2 – COST OR PRICE SUPPORT
Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section.

SECTION 3 – UNIFORM COST ASSUMPTIONS

1. Technical Cost Assumptions

A. Ongoing Activities at contract award - assume responsibility for the following:

1) Materials for a total of 100 active and 175 inactive INDs, IDEs and/or MFs requiring storage in the DMID Regulatory Management Database System and in hard copy at DMID's offices (4,000 3-inch binders and 4,500 3-inch binders, respectively).
2) A total of 10 pre-IND briefing packets in development.
3) A total of 15 original IND or IDE submissions in development.
4) A total of 2 original MF submissions in development.
5) A total of 10 Investigator Brochures in development.
6) A total of 5 Environmental Assessment Exemption statements in development.
7) A total of 5 INDs, IDEs or MFs inactivated or withdrawn.
8) A total of 75 Annual Reports due for active INDs, IDEs and/or MFs with 12 of these Annual Reports in preparation at the time of contract award.
9) One audit/site visit in the stages of preparation and 3 additional audits/site visits to be planned and conducted.
10) Two meetings with the FDA in the stages of preparation.

B. New regulatory support activities <u>during the contract period of performance – assume the following</u>:

1) *Original Regulatory Submissions*: Review, preparation and filing of 15 original INDs or IDEs and 2 MFs per year and the preparation, and submission of 15 Annual Reports per year for new INDs, IDEs and/or MFs.
2) *Subsequent Regulatory Submissions:* Review, preparation, and filing of 150 subsequent regulatory submissions to the IND, IDE or MF per year.
3) *Investigator Brochures and Environmental Assessment Exemption Statements*: Review and/or preparation of 10 Investigator Brochures and preparation of 5 environmental assessment exemption statements per year.
4) *Pre-IND and Pre-IDE Packets*: Review, preparation, assembly and submission of 10 pre-IND and/or pre-IDE briefing packets per year.
5) *FDA Meetings and Teleconferences*: 3 meetings and 7 teleconferences with the FDA per year and the preparation of summaries for all such meetings and teleconferences.
6) *Specialized Services*: Technical reviews and written comments and recommendations for 4 pharmotoxicology reports, 4 process validation reports, and 4 biological assay validation protocols and reports.
7) *Regulatory Audits*: A total of 4 two-day audits/site visits per year
8) *Regulatory Educational and Training Activities*:
   (i) The planning, conduct, and logistical arrangements for one 5-day regulatory training workshop to be held each year in the Bethesda, MD area for 100 participants.
   (ii) Preparation for and participation in 4 one-day protocol-specific clinical investigator meetings.
   (iii) Preparation for and participation in 4 one-day meetings of DMID-funded clinical research networks.
   (iv) Planning and conduct of 2 one-day regulatory training workshops and 15 regulatory training webcasts per year for an average of 25 participants per training event.

C. *Initial and Final Transition*: Include a separate breakdown of all costs associated with the Initial and Final Transition

2. Travel

A. Contract Initiation Meeting

Assume travel for the Principal Investigator (PI) and 4 key Contractor staff to participate in a one-day contract initiation meeting, to be held in the Bethesda, MD.

B. Weekly Progress Meetings

Assume travel for the PI and 4 key Contractor/subcontractor personnel to attend two half-day meetings per month at the offices of DMID.

C. Bi-Weekly Meetings with DMID Office of Regulatory Affairs (ORA)

Assume travel for the PI and 2 key Contractor/subcontractor personnel to participate in half-day bi-weekly meetings with the Project Officer and other DMID ORA staff at the offices of DMID.

D. Annual Meetings

Assume travel for the PI and 4 key Contractor/subcontractor staff to participate in annual 2-day meetings, to be held in the Bethesda, Maryland.

E. Regulatory Educational and Training Activities

1) Annual Training Workshop: Assume travel for the PI and a total of 4 presenters, including key Contractor/subcontractor staff serving as presenters, for the annual 5-day training workshop to be held in the Bethesda, Maryland area.

2) Regulatory Training Workshops: Assume travel for 3 presenters, including Contractor staff serving as presenters, for each of the 2 one-day regulatory training workshops to be conducted per year in the Bethesda, Maryland area.

3) Investigator Meetings: Assume travel for the PI and 2 key Contractor/subcontractor staff to participate in each of 4 one-day investigator meetings per year. Assume that two of these meetings will be within a 50 mile radius of Washington, DC and that two of these meetings will be held outside of the Washington, DC area within the U.S.

4) Annual Meetings of DMID-funded clinical research networks: Assume travel for the PI and 2 key Contractor/subcontractor staff to participate in each of 4 one-day investigator meetings per year. Assume that these meetings will be within a 50 mile radius of Washington, DC.

F. *Meetings with the FDA*: Assume travel for the PI and 2 key Contractor staff to participate in 10 formal meetings per year with the FDA, to be held within a 50-mile radius of Washington, DC.

3. Other

In order to utilize the data received from the regulatory support data management system, the Contractor shall include the costs for purchasing the following servers and software with the following specifications:

Web Server
Software: Microsoft Windows 2003 Server, IIS 6.0, Adobe Coldfusion MX 7.02, MacAfee Antivirus, SSL 2.0, CTi.Crypto20.DLL, CTi FolderWatcher
Hardware: Dell PowerEdge 1750, 1024 Meg Memory, 40 GIG HD space

Database Server
Software: Microsoft Windows 2003 Server, Microsoft SQL Server 2000, Microsoft Outlook Client, SSL 2.0, CTi.Crypto20.DLL
Hardware: Compaq Proliant DL380 2 GB memory, 30 GB HD space

Backup Server
*Software***:** Microsoft Windows 2003 Server, IIS 6.0, Adobe Coldfusion MX 7.02, SSL 2.0, CTi.Crypto20.DLL
Hardware: Compaq Proliant DL380 2 GB memory, 30 GB HD space

Mail Server

*Software***:** Microsoft Windows 2003 Server, ActiveMail Mail Server, SSL 2.0
*Hardware***:** Compaq DL380 G4 3 36.8 gig 1500 RPM drives, 2 gig memory, and 2.8 Intel processors

SECTION 4 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

1) Small Business Subcontracting Plan
Section L of the RFP specifies the minimum documentation requirements for completing a subcontracting plan. This plan should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

2) Extent of Small Disadvantaged Business Participation
Section L of the RFP specifies the minimum documentation requirements for small disadvantaged business utilization. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

3) Past Performance Data, including references
Section L of the RFP specifies the minimum documentation requirements for providing past performance information. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

ATTACHMENT 7
CURRENT DMID CLINICAL RESEARCH PROGRAMS

Vaccine and Treatment Evaluation Units (VTEUs)

Established in 1962, the NIAID Vaccine and Treatment Evaluation Units (VTEUs) are composed of university research hospitals across the United States that conduct Phase 1, 2, 3 and 4 clinical trials to evaluate candidate vaccines and therapeutics for a broad range of infectious diseases, including potential agents of bioterrorism. The VTEU program currently consists of the seven contracts listed below. Recompetition of the VTEU contracts is underway and awards are anticipated in early FY 2008 (see Request for Proposals at http://fs1.fbo.gov/EPSData/HHS/Synopses/3465/NIH-NIAID-DMID-08-03/NIAID-DMID-08-03RFP.pdf)

Current VTEU sites:

Baylor College of Medicine	N01-AI-25465
Cincinnati Children'sHospital Medical Center	N01-AI-25459
Harbor UCLA Medical Center	N01-AI-25463
Saint Louis University	N01-AI-25464
University of Maryland, Baltimore	N01-AI-25461
University of Rochester	N01-AI-25460
Vanderbilt University	N01-AI-25462

DMID Viral and Respiratory Pathogen Research Unit (VRPRU)

The VRPRU (Contract No. N01-AI-30039) was awarded to Baylor College of Medicine in 2003. This multidisciplinary network supports pre-clinical studies designed to provide proof-of-concept data to accelerate progression of candidate products to clinical evaluation. This contract also supports Phase I and Phase II clinical trials of vaccines and therapeutics against selected human viral respiratory pathogens, including influenza, development of relevant immunological assays, and human challenge studies with influenza viruses.

DMID Bacterial and Respiratory Pathogen Research Units (BRPRU)

The BRPRU (Contract No. N01-AI-30040) was awarded to the University of Iowa in 2003 to conduct preclinical and clinical studies including Phase 1 and Phase 2 clinical trials of vaccines, therapeutics, diagnostics, other biologics and drugs as preventive and therapeutic measures against bacterial respiratory pathogens. The focus is on translational and clinical research.

Malaria Vaccines: Clinical Research and Trial Sites in Endemic Areas

This contract (Contract No. N01-AI-40016) was awarded to Noguchi Memorial Institute for Medical Research on June 1, 2004. Subcontracts are currently in place in Ghana and Burkina Faso, through which multiple Phase 1 and Phase 2 malaria vaccine trials take place.

The Collaborative Antiviral Study Group (CASG)

The CASG is a multi-center activity supporting clinical trials of therapies for viral infections other than HIV. The Principal Investigator and the core infrastructure are located at the University of Alabama at Birmingham.

ATTACHMENT 8
DMID-FUNDED CLINICAL RESEARCH
SUPPORT SERVICES CONTRACTS

DMID Clinical Trials Management Support Contract

PPD Development, LP, located in Wilmington, NC, provides clinical trials management support to DMID and DMID investigators. PPD Development specific responsibilities include the following:

A. Clinical site assessment, evaluation of clinical sites for clinical research feasibility and capacity;
B. Clinical site preparation and clinical trial operations assistance; study document preparation and review;
C. Establish and assist clinical sites with internal quality control and quality assurance;
D. Provide Good Clinical Practice training;
E. External clinical site monitoring, including site initiation, interim and close-out visits and quality audit visits;
F. Centralized pharmacovigilance and safety monitoring; and
G. Information and document management through web-based systems.

The Clinical Trials Management (CTM) contractor provides to DMID a centralized database developed from commercial software. The CTM contractor maintains the database and the data held in the database for DMID-funded clinical trials and clinical studies. Information stored for tracking and reporting purposes includes clinical site information, clinical protocol information, inventory of essential documents for clinical sites, and schedule of clinical site visits. The CTM archives clinical site essential documents and protocols in readable pdf format on a secure website.

DMID Data Coordinating Center for Clinical and Epidemiologic Studies in Infectious Diseases

EMMES Corporation, located in Rockville, MD, provides several services for DMID-supported clinical research programs, including the following:

A. Provides statistical leadership and clinical trial design expertise for the development of protocols and the analysis of study data;
B. Establishes and administers data collection, management, quality assurance and reporting systems;
C. Provides adverse event safety reporting system and reconciles with the pharmacovigilance (SAE) system maintained by the CTM contractor;
D. Provides detailed record maintenance and timely reporting;
E. Provides an inventory and tracking system for study specimens; and
F. Collaborates with DMID, DMID-supported research groups, individual Principal Investigators and contractors.

The Data Coordinating Center contractor provides a password-protected web site for DMID-funded clinical investigators and DMID staff that contains information relating to various DMID-sponsored clinical studies. The web site provides access to the study protocols, source documents, reports, manuals of procedure, rosters, and other relevant

study materials. Also included is a link to AdvantageEDCSM, the Internet data entry system used to submit and audit data collected in the studies.

In addition, the Data Coordinating Center contractor has designed, developed and validated a secure, state-of-the-art data collection and computer-based data and study management system and related procedures, including the capacity to customize as necessary for particular studies. The system provides for receiving, entering, verifying, processing, editing (including within and between form validity, logic and consistency checks), updating, correcting, storing, tracking, retrieving and analyzing data. The system allows management of all study data from the various clinical and laboratory sites, adverse event tracking across studies, study logistics, study status reporting and clinical project tracking.

This contract is being recompeted for award in FY 2008. A copy of the Request for Proposals for this initiative, the Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases, can be found at: http://www.fbo.gov/spg/HHS/NIH/NIAID/RFP%2DNIH%2DNIAID%2DDMID%2D08%2D04/Attachments.html.

DMID Regulatory Affairs Support Contract

Currently awarded to Fisher BioServices Corporation, located in Rockville, MD., the DMID Regulatory Affairs Support contract provides regulatory and clinical agent and clinical sample repository support services, including:

A. Preparation and maintenance of Investigational New Drug (IND) applications;
B. Preparation and maintenance of Investigational Device Exemptions (IDE)
C. Consulting and auditing for manufacturers of DMID investigational products;
D. Management and operation of a clinical agent repository for distribution and tracking of clinical agents; and
E. Management and operations of a clinical specimen repository for DMID-supported clinical trials.

The current DMID Regulatory Affairs Support contractor utilizes two DMID-owned database management systems, the Clinical Agent Repository Inventory Management (CARIM) system and the Human Subjects Research Oversight Accountability Database (HSROAD). HSROAD is a centralized web-based IND/IDE management database that captures and tracks a variety of regulatory-related data for DMID, including: 1) the progress of IND/IDE clinical trials from concept through protocol implementation, modification, and final reporting; 2) the documentation of receipt and dates of filing regulatory documents to the IND/IDE; 3) name and contact information for pertinent individual sites and investigators; 4) the products and lot numbers being used in DMID-funded clinical research; 5) the receipt of all essential documents to allow shipping of product to clinical sites, and 6) electronic ordering of clinical agents from DMID-funded clinical research sites.

CARIM is a web-based clinical agent inventory management database system for the receipt, processing, tracking, shipping, inventory control, and activity report-generation, of clinical agents used in DMID-funded clinical research. CARIM consists of several major modules and an administrator module. The major modules contain user interfaces, processes, and a centralized data repository to capture and manage the data

related to the management of a clinical agent inventory. The CARIM database was developed following best practices for relational database design, data normalization, and development; and is deployed on the Microsoft SQL Server 2000 database server. The Web server software is Microsoft's Internet Information Services 6.0 (IIS). The ColdFusion Enterprise MX application server is used to connect the Web application to the database and to provide dynamic content for the browser-based CARIM application. All the architecture is based on the Microsoft Windows 2003 server software. The application is targeted for users with Microsoft's Internet Explorer version 5.0 or greater, or Netscape's Navigator version 8.0 or greater.

The HSROAD and CARIM system descriptions can be found at: http://www.niaid.nih.gov/research/resources/DMIDClinRsrch/links.htm.

The regulatory affairs support contract currently being performed by Fisher BioServices Corporation is being recompeted as a separate contract for award in FY 2008. When available, a copy of the Request for Proposals will be posted at: www.niaid.nih.gov/contract/rfps.htm.